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Caring for Someone with Acquired Brain Injury:
the Role of Psychological Flexibility and
a Systematic Review of Remotely Delivered
Interventions

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Thesis Abstract

To care for someone with an Acquired Brain Injury (ABI) can be a valued role in one's life, and caregivers play a key role in the rehabilitation process. Unfortunately, caregivers of people with ABI have also been found to report greater levels of psychological distress and worse wellbeing compared to the general population.

The first chapter of this thesis reports findings from a cross-sectional study exploring the role of psychological flexibility in depression, anxiety and satisfaction with life amongst ABI carers. The aim of the study was to investigate the relative strength of psychological flexibility in explaining caregiver outcomes compared to established constructs, namely cognitive appraisals, coping, social support and the perceived functional disability of the care-recipient. Psychological flexibility was found to predict most of the variance in depression and anxiety, whilst cognitive appraisal was the strongest predictor of satisfaction of life. Cognitive appraisal mediated the influence of functional disability on all outcomes, and this mediating effect was moderated by psychological flexibility on depression. Chapter one concluded that psychological flexibility appears to have a central role in psychological distress amongst ABI carers, which is adding to our understanding of how to support this population.

Chapter two presents a systematic review of the evidence for remotely delivered interventions to improve the wellbeing of ABI carers. Twelve studies were identified from systematic searches. These studies evaluated a wide range of interventions that were being offered to caregivers remotely using various modes of delivery. Promising results were found on primary and secondary wellbeing outcomes. However, due to a limited number of studies it was concluded that it is currently not feasible to make any general conclusions on

the efficacy of specific interventions being delivered remotely for this population. Besides, in many studies low-intensity support was potentially as effective as a structured programme. Methodological issues were discussed, and specific recommendations for future research and developments in the field were provided.

Combined, the two chapters of this thesis have identified that psychological flexibility appears to play a central role for outcomes amongst ABI carers, and that remote delivery is a promising field with the potential to improve wellbeing for this population.

Lay Summary

To provide informal care to someone with an Acquired Brain Injury (ABI) can be associated with many positive experiences. Unfortunately, caring can also involve a lot of practical and emotional stress, which can have a negative impact on someone's wellbeing.

This thesis consists of two chapters that together explore the topic of wellbeing amongst caregivers of adults who have suffered from an ABI. The first chapter describes a research study. The aim of the study was to explore different factors and their role in explaining distress and wellbeing amongst caregivers of adults with ABI. The study found that a concept called psychological flexibility and the caregiver's interpretation of their situation both were important for their wellbeing. These findings strengthen our understanding of caregiver wellbeing, and it is hoped this can inform the development of future support interventions.

The second chapter presents an overview of research studies that test if support to caregivers of people with ABI can be delivered remotely. In total, twelve studies were found that explored various ways of supporting the wellbeing of ABI carers from a distance. In summary, encouraging outcomes were identified and remote delivery is a promising way of improving access to support for this group. The review also found that there were some issues in how the research was carried out that limited the conclusions from these findings.

Combined, this thesis concluded that psychological flexibility is an important concept when understanding wellbeing amongst ABI carers, and that support for this group could be delivered remotely.

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Terminology

Throughout this thesis, a caregiver is defined as someone who provides personal care, help and assistance in an informal capacity. As such, this definition incorporates significant others, family members, friends or anyone else who provides this type of support to someone with an acquired brain injury, or any other condition or illness. This definition does not include a person who provides care and support as part of a paid role. The terms *caregiver* and *carer* are used interchangeably throughout this thesis.

Chapter One

Caring for Someone with an Acquired Brain Injury: the Role of Psychological Flexibility

Title page*

Title: Caring for Someone with an Acquired Brain Injury: the Role of Psychological Flexibility

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Abstract

This study explores the role of psychological flexibility in depression, anxiety and satisfaction with life amongst caregivers of adults with Acquired Brain Injury (ABI). The predictive power of psychological flexibility was examined in comparison to established constructs known to explain variance in caregiver outcomes (functional disability of care-recipient, perceived burden, social support and coping). Using a quantitative cross-sectional design, 145 caregivers of adults with ABI completed self-report measures through an online survey. Data were analysed using correlation, hierarchical multiple regression and conditional process analysis to explore the relationships between predictor variables and outcomes. Correlations generally demonstrated associations between psychological flexibility, established constructs and caregiver outcomes in predicted directions. Hierarchical regression analysis indicated that psychological flexibility was the strongest predictor of depression ($\beta = -.37, p < .001$) and anxiety ($\beta = -.38, p < .001$), whilst caregiver appraisals predicted most variance in satisfaction with life ($\beta = -.34, p < .001$). Conditional process analysis demonstrated that caregiver appraisals mediate the relationship between the care-recipients functional disability (as perceived by the caregiver) and caregiver outcomes, as predicted. Psychological flexibility moderates the mediating effect of appraisals on depression, whilst problem-focused coping moderates the mediating effect of appraisals on satisfaction with life. Psychological flexibility, caregiver appraisals and avoidant coping are modifiable factors predicting depression, anxiety and satisfaction with life. These constructs could be potential targets for future interventions, such as Acceptance and Commitment Therapy or traditional Cognitive Behavioural Therapy. Psychological flexibility is a promising concept that adds to previous conceptualisations of caregiver wellbeing and distress.

Introduction

Acquired Brain Injury (ABI) refers to any sudden injury to the brain that occurred following birth, and includes aetiologies of closed or penetrative head injuries and medical conditions. Common ABIs are Traumatic Brain Injury (TBI), stroke, encephalitis, meningitis, brain tumour and anoxic injury as a result of oxygen deprivation. ABI is a considerable public health problem and one of the leading causes of lifelong disability globally (Chan, Parmenter, & Stancliffe, 2009; Teasell et al., 2007). In addition to physical and sensory impairments, ABI can result in significant impairment of functioning in domains including cognition, behaviour and emotional regulation (Lezak, Howieson, & Loring, 2004). The consequences of ABI can be catastrophic and long-standing, affecting whole families (Ponsford, Olver, Ponsford, & Nelms, 2003; Turner et al., 2007).

Following an ABI, family and friends often take on the role of caregiver in various capacities including emotional support, medical care and assistance with activities of daily living (Talley & Crews, 2007). Caring for someone with ABI has distinct challenges compared to other chronic conditions, and calls have been made for research into the specific context of this population (Jackson, Turner-Stokes, Murray, Leese, & McPherson, 2009; Lincoln, Kneebone, Macniven, & Morris, 2011). The most obvious distinction to conditions such as dementia or developmental disabilities is the sudden onset of a brain injury, which is a common factor across aetiologies under the ABI umbrella. Depression, anxiety and reduced quality of life (QoL) is more prevalent amongst caregivers of adults with ABI compared to the general population, and tends to persist over time (Calvete & De Arroyabe, 2012; Kreutzer, Rapport, et al., 2009; Loh, Tan, Zhang, & Ho, 2017; Ponsford & Schönberger, 2010). In fact, when compared to other chronic conditions, such as cancer and dementia, caregivers of people with ABI report worse outcomes (Harding et al., 2015; Jackson, Turner-

Stokes, Murray et al., 2009). Caregiver distress has also been found to impact negatively on the neuropsychological recovery of the survivor which highlights the importance of research into the effects of ABI beyond the individual patient (Covey, Noble, & Schenk, 2013; Greenwood, Mackenzie, Cloud, & Wilson, 2008; Vogler, Klein, & Bender, 2014).

Although distress is common amongst caregivers of people with ABI, not everyone suffers adverse outcomes (Wells, Dywan, & Dumas, 2005). Caring has been linked to personal growth and other positive outcomes (Cohen, Colantonio, & Vernich, 2002). Further research is needed in order to better understand and predict outcomes, and ultimately to advance interventions designed to minimise distress and enhance wellbeing amongst this population.

Predictors of Caregiver Outcomes

Clinical factors such as severity of the injury, time since the injury or type of ABI appear to be weak predictors of psychological distress and wellbeing of the caregiver beyond the acute phase (Bermejo-Toro et al., 2020; Jackson et al., 2009; Kreutzer, Gervasio, & Camplair, 1994; Sander, High, Hannay, & Sherer, 1997). The level of functional disability of the survivor, as perceived by the caregiver, has however been associated with caregiver distress and QoL (Chronister et al., 2016; Kreutzer, Serio, & Bergquist, 1994).

Psychological variables of the caregiver are of particular interest due to the potential to modify these to alleviate suffering and improve wellbeing. Despite a consistent growth in publications in this area, a lack of a unifying theoretical framework limits our ability to synthesise and translate findings from process research into interventions. Suitable theoretical frameworks for this purpose could be the Stress-Process Model (SPM) and the Psychological Flexibility model.

The Stress-Process Model

Based on Lazarus and Folkman's (1984) stress and coping theory, the Stress-Process Model (SPM) has been proposed to explain distress amongst caregivers of people with TBI (Chronister & Chan, 2006; Chwalisz, 1992) and stroke (Bakas & Burgener, 2002). The model suggests that caregiver distress is dependent on how the caregiving situation is appraised and what coping skills and resources are accessible to the individual (Chwalisz, 1996).

Within the SPM, perceived burden has been conceptualised as the individual's subjective negative *appraisal* of the stressful caregiving situation (Chwalisz, 1996). This includes beliefs that the demands of caregiving are overwhelming, unending, depleting and that the caregiver is isolated, not doing a good enough job, and have lost control of their life. Caregiving mastery and satisfaction have also been suggested as part of the caregiver appraisal construct, although it is less clear how and to what degree these predict outcomes (Lawton, Moss, Kleban, Glicksman, & Rovine, 1991; Struchen, Atchison, Roebuck, Caroselli, & Sander, 2002). Perceived burden has consistently been found to predict psychological distress and QoL in caregivers of people with ABI (Bakas & Burgener, 2002; Chronister, Chan, Sasson-Gelman et al., 2010; Harris, Godfrey, Partridge et al., 2001; Sander et al., 1997). According to the SPM, negative appraisal (i.e. perceived burden) has a mediating role between caregiving stressors (e.g. disability of the care-recipient) and outcomes (Chronister et al., 2016; Harris et al., 2001).

A further element of the SPM is coping. Coping strategies have been linked to caregiver outcomes, but less is known with regards to what constitutes effective coping among caregivers of ABI or how coping styles interact with other concepts in the model (Kendall & Terry, 2008). For example, it has been suggested that problem-focused coping (e.g. taking action, seeking advice, problem-solving) is associated with reduced distress in caregivers of people with TBI (e.g. Chwalisz, 1996), whereas other studies have found the

opposite effect (e.g. Chronister & Chan, 2006). Similar inconsistencies have been found for emotion-focused coping (e.g. positive reframing, acceptance, emotional support; Chronister & Chan, 2006; Chwalisz, 1996; Sander et al., 1997). Avoidant coping (e.g. denial, distraction, substance use) has more consistently been associated with poor psychological adjustment and reduced QoL in caregivers of people with ABI (Blankfeld & Holahan, 1999; Chronister et al., 2010; Wade et al., 2001).

Social support is a well-known buffer against stress, and social isolation can exacerbate already difficult circumstances (Cobb, 1976; Manskow et al., 2015). Social support includes practical support, such as help with care tasks, housework or transportation, as well as emotional support and social contact. Social support has been found to moderate outcomes amongst ABI caregivers (Chronister et al., 2010; Ergh, Rapport, Coleman, & Hanks, 2002; Harris et al., 2001). Chronister and colleagues (2016) found that social support moderated the relationship between perceived burden and QoL, suggesting that caregivers who appraise their circumstances as burdensome can still maintain their wellbeing through social support.

Constructs from the SPM would be potential targets for psychological interventions to improve the wellbeing of caregivers. With a focus on cognitive appraisals and coping strategies, Cognitive Behavioural Therapy (CBT) has been suggested as a suitable intervention involving cognitive restructuring, adaptive strategies and psychoeducation (Bakas & Burgener, 2002; Stebbins & Pakenham, 2001). There is a lack of controlled trials investigating CBT for caregivers of adults with ABI, and no specific CBT model for caregiver distress exists. Interventions consisting of specific elements from the CBT framework, such as skill-building or problem-solving, have been promising but less effective for psychological distress and QoL (Boschen, Gargaro, Gan, Gerber, & Brandys, 2007; Kreutzer, Stejskal, et al.,

2009; Panzeri, Ferrario, & Vidotto, 2019). Although the SPM has established key factors to explain outcomes, research into concepts that could directly link theory to intervention for this population is still needed (Boschen et al., 2007). A potential candidate from outside of the SPM is psychological flexibility, which is a more recent concept with a growing relevance to our understanding of wellbeing amongst caregivers.

Psychological Flexibility

Psychological flexibility can be defined as an individual's ability to openly experience internal and external events, and to behave in line with personal values even under difficult circumstances (Harris, 2006). Psychological *inflexibility* is the opposite and can thus be summarised as "the inability to persist or change behaviour in the service of long-term valued ends", and is thought to be a core process in psychopathology (Hayes, Luoma, Bond, Masuda, & Lillis, 2006, p. 6). Psychological flexibility involves six overlapping and interdependent processes together referred to as the Hexaflex model: defusion, acceptance, present moment awareness, values, committed action, and self as context (Hayes et al., 2006). More recently, psychological flexibility has been conceptualised as three clusters (open, aware and active) where flexibility is thought to increase through a more open, aware and engaged approach to life (Hayes, Strosahl, & Wilson, 2012).

The psychological flexibility model has direct links to intervention, namely Acceptance and Commitment Therapy (ACT), of which the aim is to foster psychological flexibility. ACT is an empirically-based behavioural therapy under the umbrella term of CBT (Twohig, 2012). However, a key distinction to conventional cognitive therapy (e.g. Beck, 1976) is that ACT targets the *function* of internal events, such as emotions and thoughts, rather than striving towards altering the *content* of these (Hayes, Strosahl, & Wilson, 1999).

The aim in ACT is to learn how to live well in the presence of internal events whilst actively engaging in value-driven behaviour.

Higher levels of psychological flexibility have been associated with improved wellbeing and lower levels of distress in clinical samples and in the general population (Daks & Rogge, 2020; Graham, Gouick, Ferreira, & Gillanders, 2016; Kashdan & Rottenberg, 2010; Stabbe, Rolffs, & Rogge, 2019; Twiselton, Stanton, Gillanders, & Bottomley, 2020). ACT has been found to be an effective intervention for a range of conditions, particularly chronic conditions (A-Tjak et al., 2015; Gloster, Walder, Levin, Twohig, & Karekla, 2020; Graham, Gouick, Krahé, & Gillanders, 2016). Studies investigating change mechanisms have found that ACT works through increasing psychological flexibility (Ruiz, 2012; Stockton et al., 2019; Wicksell, Olsson, & Hayes, 2010).

Conceptually, the psychological flexibility model could add to the SPM. The role of cognitions such as appraisals, beliefs and self-critical thoughts are evidenced in the literature and by the SPM (Chronister et al., 2016; Riley, 2007). From a traditional cognitive perspective, the distressed caregiver's appraisal would be regarded as an irrational or dysfunctional interpretation, and the corresponding treatment would be to reduce or alter these (Beck, 1976; Stebbins & Pakenham, 2001). Similarly, cognitive processes such as catastrophising or dichotomous thinking are challenged and modified. However, negative appraisals in caregiving are not necessarily irrational, or magnified, but rather reflective of a long-term and highly challenging context, arguably similar to a chronic health condition. From the lens of the psychological flexibility model, the focus lies instead on the function of appraisals and their impact on behaviour. Caregivers with a more flexible stance towards appraisals are thought to be less behaviourally affected by them, which allows for

engagement in valued behaviour instead of avoidance strategies (Romero-Moreno, Losada, Márquez-González, & Mausbach, 2016).

ACT has shown promise in alleviating distress in individuals caring for someone with dementia (Collins & Kishita, 2019; Kishita, Hammond, Dietrich, & Mioshi, 2018; Márquez-González, Romero-Moreno, & Losada, 2013). Losada and colleagues (2015) compared ACT to conventional CBT in a Randomised Controlled Trial (RCT) with dementia caregivers and found both interventions efficacious for depression and anxiety. Findings from cross-sectional studies demonstrate that higher levels of psychological flexibility is associated with greater satisfaction of life amongst dementia caregivers (Romero-Moreno, Márquez-González, Losada, Fernández-Fernández, & Nogales-González, 2015; Spira et al., 2007). Jansen and colleagues (2017) found that levels of psychological flexibility predicted distress in caregivers of people with psychosis even when controlling for established constructs, such as perceived burden. Findings from a meta-analysis suggest that ACT can improve psychological flexibility amongst caregivers, with moderate to large effects (Han, Yuen, Lee, & Zhou, 2020). To date, no RCT has been conducted to investigate the efficacy of ACT for caregivers of adults with ABI, and no cross-sectional study has been published on the role of psychological flexibility in this specific population. Similarly, few studies have compared the psychological flexibility construct to established caregiver constructs, such as appraisals.

Williams and colleagues (2014) published a qualitative preliminary investigation into the experience of five spousal caregivers of adults with ABI taking part in an ACT group. Participation in the group was reported to be beneficial as it helped facilitate awareness and acceptance of difficult emotions and thoughts involved in the caregiving experience. Qualitative accounts have outlined acceptance, living in the present and engagement in value-based behaviours as themes linked to better adjustment (Abrahamson, Jensen,

Springett et al., 2017; Hayas, De Arroyabe, & Calvete, 2015; Lond & Williamson, 2018).

Psychological flexibility theory provides a framework, directly linked to intervention, that could add to the SPM and our understanding of caregiver outcomes. However, there is a lack of research into the role of psychological flexibility, or ACT, for caregivers of people with ABI.

The Present Study

The aim of the present study was to explore the role of psychological flexibility in depression, anxiety and satisfaction with life amongst caregivers of adults with ABI.

The SPM has defined relevant psychological concepts such as perceived burden, social support and coping, and their demonstrated influence on caregiver outcomes. Similarly, the perceived functional disability of the person being cared for has been directly linked to wellbeing outcomes of the caregiver. This study therefore investigated the relative strength of psychological flexibility, and its role, in explaining caregiver outcomes compared to the established constructs of functional disability, perceived burden, social support and coping.

In three hierarchical multiple regressions, it was predicted that psychological flexibility would explain unique variance in outcomes (i.e. anxiety, depression and life satisfaction) when well established factors of perceived burden, coping, social support and care-recipient functional disability were accounted for in the models. To further explore the specific role of psychological flexibility, in relation to the constructs from the SPM, conditional process analysis was used. Firstly, in a simple mediation model it was predicted that perceived burden would mediate the direct relationship between the perceived functional disability of the care-recipient and caregiver outcomes, in accordance with the SPM. Secondly, it was predicted that psychological flexibility, coping and social support would each moderate the indirect effect of perceived burden on outcomes. This was tested

with a moderated mediation model for each of the predicted moderators (i.e. psychological flexibility, coping and social support) on each outcome.

Methods

Design

The present study was a quantitative cross-sectional design. The study protocol was pre-registered (Rickardsson, Gillanders, Scotland, & Poveda, 2019). Participants completed an online survey consisting of a battery of standardised questionnaires measuring satisfaction with life, psychological distress, functional disability of the care-recipient, psychological flexibility, coping, social support and perceived burden. Demographic information was gathered as part of the online survey including information about the caregiver, the care-recipient, the ABI and the caregiver context. All responses were anonymised, and informed consent was obtained from each participant. Full ethical approval was obtained from an NHS Research Ethics Committee (ref: 19/NI/0215).

Recruitment

Participants were recruited through convenience sampling between March and December 2020. Several UK-wide brain injury organisations (e.g. Headway, Encephalitis Society, Meningitis Now, SameYou, the Disability Trust, Braintrust) advertised the study online on social media platforms (Twitter and Facebook).

Initially, additional recruitment was planned to take place across a local neuropsychology department and a local Headway service using pen and paper versions of the survey. However, due to restrictions relating to the COVID-19 pandemic, no participants were recruited in person.

Participants

Caregivers self-identified as eligible to participate. Informal caregivers over the age of 16 could participate if they could comprehend written English and cared for an adult who had suffered an acquired brain injury after the age of 16, and who had been discharged from hospital for more than three months. The exclusion criterion was if someone cared for a person with a degenerative or progressive brain injury (e.g. dementia or multiple sclerosis). 145 participants completed the survey and all met criteria for inclusion.

Measures

Dependent Variables

The Depression Anxiety Stress Scale – short version (DASS-21). DASS-21 is comprised of 21 self-report items measuring three separate constructs of psychological distress with 7 items for each construct: depression; anxiety; and stress (Antony, Cox, Enns et al., 1998; Lovibond & Lovibond, 1995). Higher scores indicate greater level of distress. The subscales have been shown to have good internal consistency with Cronbach's alphas of .88, .82, and .90 for the depression, anxiety and stress scale respectively (Henry & Crawford, 2005). Cronbach alpha values for the present sample were .91 for depression, .81 for anxiety, and .86 for stress.

Satisfaction With Life Scale (SWLS). The SWLS is a self-report scale containing 5 items designed to assess perceived global life satisfaction (Diener, Emmons, Larsem et al., 1985). Higher scores indicate better life satisfaction. The scale has been found to have good internal consistency ($\alpha = .87$) (Diener, Inglehart, & Tay, 2013). The internal consistency for the present study was .88.

Predictor Variables

The Patient Competency Rating Scale – Relative version (PCRS – R). The PCRS-R assesses functional competency of the care-recipient, as perceived by the caregiver (Prigatano, 1986). For the present study the scoring was reversed to represent functional disability of the care-recipient, as perceived by the caregiver. Higher scores therefore correspond to greater functional disability. The scale has high internal consistency ($\alpha = .93$), and has been used as a measure for functional disability in previous research on ABI caregivers (Chronister et al., 2016; Ergh et al., 2002; Prigatano, Altman, & O'Brien, 1990). Cronbach alpha value for the present study was .94.

Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT). The CompACT is a self-report scale designed to assess psychological flexibility (Francis, Dawson, & Golijani-Moghaddam, 2016). The scale comprises of 23-items, and higher scores indicate greater psychological flexibility. The scale consists of three subscales assessing specific, but inter-related processes involved in the overarching concept of psychological flexibility namely: Openness to Experience, Behavioural Awareness and Valued Action. For the present study, the total score was used. The CompACT has been found to have excellent ($\alpha = .91$) internal consistency (Francis et al., 2016). Alpha coefficient in the present sample was .88.

The Brief Coping Orientation to Problems Experienced (COPE) scale. The brief COPE is a self-report questionnaire measuring coping strategies (Carver, 1997). Covering 3 domains; emotion-focused; problem-focused and avoidant coping, each subscale has acceptable internal consistency on their own ($\alpha = 0.72, 0.84, 0.75$, respectively) in previous caregiver samples (Cooper, Katona, & Livingston, 2008). The full scale comprises of 28 items and higher scores on a subscale indicate more frequent use of the coping style. Alpha

coefficients in the present sample were .71, .80 and .73 for emotion-focused, problem-focused and avoidant coping respectively.

The Interpersonal Support Evaluation List-12 (ISEL-12). The ISEL-12 consists of 12 self-report items assessing perceived available social support (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). Higher scores indicate greater perceived social support. Internal consistency has been reported as acceptable ($\alpha = .77$), and the scale has been widely used in ABI caregiver samples to assess social support (Chronister et al., 2010; Cohen & Hoberman, 1983; Stevens et al., 2013). The Cronbach alpha value was .91 in the present sample. The language on some items was adapted to suit a UK demographic (e.g. the word *apartment* was changed to *flat*), and a minor modification was made to the instructions for clarity. The modification to the instructions highlighted to participants that some items include activities which caregivers may find hard to imagine doing due to time constraints (e.g. *'If I wanted to have lunch with someone, I could easily find someone to join me'*), but that the questionnaire was interested in the social aspect of each item.

The Modified Caregiver Appraisal Scale (MCAS). The MCAS is a self-report scale measuring appraisals related to the caregiving situation (Struchen, Atchison, Roebuck et al., 2002). The complete MCAS is comprised of 35 items assessing four aspects of the appraisal construct: perceived caregiving burden; mastery; satisfaction and ideology. For the present study, the perceived burden subscale was used to measure caregiver appraisal. The decision to only use this subscale was based on perceived burden being the strongest predictor of outcomes from previous research, and in order to minimise participation burden. The subscale consists of 15 items, and higher scores indicate greater perceived burden. The subscale is widely used on its own in ABI caregiver research with good internal consistency ($\alpha = .91$) and convergent validity with other subjective burden scales (Chronister et al., 2010;

Lawton, Kleban, Moss, Rovine, & Glicksman, 1989; Struchen et al., 2002). For the present study, the Cronbach alpha coefficient was .92.

Data Analysis Plan

Preliminary analysis

The final sample was 144 after excluding one complete case due to 96% missing data for this particular case. No other case had more than 3% missing data. The remaining amount of missing data in the final sample ($N = 144$) was 0.1%. Visual inspection of a missing data analysis indicated that data were Missing Completely At Random (MCAR). The assumption that data were MCAR was further corroborated by Little's MCAR test ($\chi^2 = 1743.719$, $df = 1742$, $p = .484$ ns). A low amount of missing data (< 5%) in combination with data MCAR suggests that a maximum likelihood approach is an appropriate method to impute missing data (Enders, 2011; Newman, 2014). The Expectation Maximisation (EM) algorithm in SPSS was used to impute missing data on these assumptions. The assumptions for parametric analysis were met. Visual inspection of histograms and P-P plots indicated normal distribution of data on all variables, which was confirmed by Skewness and Kurtosis indexes which all were between -2 to +2 and -7 to +7, respectively (Hair, Black, Babin, & Anderson, 2010; Tabachnick & Fidell, 2012). All data analyses were conducted using SPSS (version 25: IBM Corp., 2017).

Covariates

Differences between demographic groups and sample characteristics were explored to identify covariates to control for in subsequent analyses. Analysis of variance (ANOVA) was used to examine group mean differences of categorical variables on dependent variables. Correlation coefficients (Pearson's r) between continuous demographic variables and dependent variables were explored.

Correlation

Correlational analysis (Pearson's r) was used to examine the relationship between key study variables. Cohen's (1992) definition of effect sizes was used (i.e. 0.1 = weak, 0.3 = moderate, 0.5 = strong). The correlation analysis influenced which variables to include in regression models.

Regression

Three hierarchical multiple linear regression analyses were conducted to explore predictors on each of the dependent variables. Hierarchical regression allows for exploration of more recent constructs whilst established theory-based concepts are accounted for. The predictive variance of established constructs is accounted for in the initial steps of the regression analysis, and the subsequent steps evaluate the additive contribution of predictors above and beyond variables entered in previous steps. As such, it is a suitable approach to explore the incremental validity of a new construct of interest, such as psychological flexibility. The assumptions for regression analyses were met for each analysis (Field, 2013). This included checks for homoscedasticity, linearity, independence and normality of errors, and absence of multicollinearity. Effect sizes reported were calculated using $f^2 = \text{adj}R^2 \setminus 1 - \text{adj}R^2$.

Conditional Process Analysis

Conditional process analysis was used to explore the specific roles of, and relationships between, psychological flexibility and established constructs from the SPM on depression, anxiety and satisfaction with life. Simple mediation models were used to statistically test if disability of the care-recipient (measured by the PCRS-RV) predicted depression, anxiety and satisfaction of life, and if this relationship was mediated by perceived burden (i.e. appraisal of the caregiver situation). Separate moderated mediation

models were used to test if coping, social support and psychological flexibility would moderate the influence of perceived burden on outcomes. The models were selected apriori based on theory and previous research, and the correlation and regression analysis also influenced what predictors to include in each model. All models were tested using Hayes (2017) PROCESS macro version 3.0 for SPSS version 25.

Power

Power estimations were conducted a-priori. From a calculation using G*power 3.1 (Faul, Erdfelder, Lang & Buchner, 2007) it was estimated that a minimum sample of $N = 103$ was required to achieve sufficient power ($\pi = 0.80$) to detect a medium effect size with seven predictors (functional disability, perceived burden, coping [avoidant, emotion- and problem-focused coping], social support and psychological flexibility) in the regression analysis. In addition, Green's rule of thumb was considered which suggests $N > 104 + m$, where m is number of predictors (Green, 1991). From this rule, a minimum sample size of 111 would be sufficient to detect a medium effect. For the conditional process analyses, Fritz and MacKinnon (2007) was referred to in order to determine a sample size that would achieve enough power (.80) to detect a medium effect size in a simple mediation model. According to this source, a minimum sample size of 75 would be required.

Results

Description of Sample

The analysed sample consisted of 144 caregivers, of which the majority (87%) identified as female. Sample characteristics are described in detail in Table 1.1, with descriptive statistics for key variables in Table 1.2. These two tables also present comparison demographics and data from similar populations. Most caregivers were employed in some

capacity (66%), and the majority were spouses (65%). Seventy-nine percent of the sample had no access to professional caregivers and the majority (70%) reported that they were the only person providing care to the care-recipient. Mean age of caregivers ($M = 50.90$) and mean age of people being cared for ($M = 49.42$) differed by little over one year, with caregivers being slightly older. There was a good mixture of ABIs represented in the sample.

The current sample was comparative to data reported by Jackson and colleagues (2009) in terms of caregiver gender, age and relationship to the care-recipient. There were some differences in terms of proportions of caregivers of different types of ABIs and the time since the injury was less in the present sample. The sample in the study by Jackson and colleagues (2009) was based on a similar conceptualisation of ABI as inclusion criteria as the present study, and participants were recruited via UK-wide charity organisations. In contrast to the present sample, the Jackson (2009) study recruited carers whose family member had recently been discharged from a local specialist rehabilitation hospital. The present study only included caregivers providing care to someone who had been discharged from hospital for more than three months. Table 1.1 provides details on both samples for comparison.

In terms of outcome variables, the present sample had greater mean anxiety and depression scores, and lower mean satisfaction of life compared to data from comparative samples (Ergh et al., 2002; Simpson, Anderson, Jones, Genders, & Gopinath, 2020).

Table 1.1 Characteristics of the sample

Variable	<i>n</i>	%	Mean	<i>SD</i>	Comparative data		
					<i>M</i>	<i>SD</i>	%
Age	144		50.9	11.7	54 ^a	10.9 ^a	
Gender							
Female	125	87					81 ^a
Male	17	12					19 ^a
Other	1	1					
Status of employment							
Full time	64	44					
Part-time due to caring responsibilities	14	10					
Part-time due to other reasons	10	7					
Unemployed due to caring responsibilities	26	18					
Unemployed due to other reasons	7	5					
Student	3	2					
Retired	20	14					
Role of caregiver							
Parent	28	19					37 ^a
Spouse	94	65					59 ^a
Child	13	9					2 ^a
Sibling	8	6					2 ^a
Friend	1	1					-
Time spent caring daily							
1-3 hours	42	29					
3-6 hours	33	23					
6-9 hours	14	10					
9-12 hours	10	7					
12-24 hours	44	31					
Care from professional (paid) carers							
Professional care	30	21					
Hours per week			34.63	49.03			
No professional care	114	79					
Help from additional informal caregivers							
Others also help	43	30					
No other informal caregivers	101	70					
Additional caring responsibilities							
Solely caring for one person with ABI	92	64					
Caring for additional individuals	49	34					
Age of care-recipients	144		49.42	15.36	46 ^a	13.5 ^a	
Years since injury			5.19	4.71	10 ^a		
Type of ABI							
TBI	40	28					49 ^a
Stroke	31	22					26 ^a
Brain tumour	16	11					-
Infectious (e.g. encephalitis and meningitis)	48	33					18 ^a
Anoxia/Hypoxia	3	2					4 ^a
Aneurysm	6	4					-

Note. a = Jackson et al. 2009

Table 1.2 Descriptive Data on Predictor Variables and Outcomes

	Scale Range	Min	Max	<i>M</i>	<i>SD</i>	Comparative data	
						<i>M</i>	<i>SD</i>
<i>Dependent Variables</i>							
SWLS Satisfaction with life	5-35	5	31	16.03	6.94	23.51 ^a	5.28 ^a
DASS Anxiety	0-21	0	21	5.42	4.27	2.31 ^b	2.74 ^b
DASS Depression	0-21	0	21	8.34	5.64	3.14 ^b	3.82 ^b
<i>Predictor Variables</i>							
PCRS-R Functional disability of CR	30-150	45	143	96.22	20.50	95.20 ^c	21.85 ^c
CompACT Psychological flexibility	0-138	24	134	69.31	20.94	not available	
COPE Problem-focused coping	6-24	6	24	15.83	3.89	21.41 ^d	4.79 ^d
COPE Emotion-focused coping	10-40	13	38	24.19	5.13	36.53 ^d	7.73 ^d
COPE Avoidant coping	12-48	12	38	23.56	5.36	18.97 ^d	4.98 ^d
ISEL Social support	12-48	12	48	31.61	8.97	35.74 ^e	na
MCAS Perceived burden	15-75	17	75	51.28	12.77	not available	

Note. CR = Care Recipient

a = Ergh et al. 2003; b = Simpson et al. 2020; c = Chronister et al. 2016; d = Chronister et al. 2010; e = Perrin et al. 2013

Covariates

For depression, significant mean group differences were found on time spent caring with the group spending more than twelve hours caring each day reporting greater levels of depressive symptoms. Similarly, caregivers who did not have help from additional caregivers reported greater levels of depression. Higher age of the care-recipient was also significantly correlated with greater levels of caregiver depression. These three factors were entered into the regression model for depression as covariates. For anxiety, no covariates were identified. For satisfaction with life, significant mean group differences were found on time

spent caring with the same pattern as for depression. The age of the caregiver and the age of the care-recipient also significantly correlated with satisfaction with life. These three variables were entered into the regression model for satisfaction with life as covariates.

Correlation Analysis

Pearson's correlation coefficients are presented in Table 1.3. Moderate to strong correlations were found between predictors in theorised directions. The exception was for coping variables (subscales of the brief COPE). Contrary to prediction, problem-focused coping did not correlate significantly with depression or anxiety. Similarly, emotion-focused coping was not associated with levels of anxiety. Only variables that had a statistically significant correlation with outcomes were included in subsequent regression models. The coping sub-scale with the strongest correlation, or theoretical basis, was selected for inclusion in each regression model. These decisions were taken in order to limit the number of variables in the regression analysis to focus on the most relevant constructs, whilst preserving power to minimise the risk of type II errors (Tabachnick & Fidell, 2012).

Table 1.3 Correlation Matrix of Predictor Variables and Outcomes

	1	2	3	4	5	6	7	8	9	10
1. SWLS Satisfaction with life	1									
2. DASS Depression	-.47**	1								
3. DASS Anxiety	-.24**	.74**	1							
4. PCRS-R Functional Disability of CR	-.48**	.38**	.36**	1						
5. MCAS Perceived burden	-.61**	.54**	.33**	.47**	1					
6. ISEL Social Support	.48**	-.48**	-.29**	-.28**	-.58**	1				
7. COPE Problem-focused coping	.28**	-.14	-.05	-.10	-.12	.31**	1			
8. COPE Emotion-focused coping	.27**	-.30**	-.16	-.08	-.19*	.34**	.57**	1		
9. COPE Avoidant coping	-.28**	.48**	.43**	.06	.40**	-.29**	-.10	-.23**	1	
10. CompACT Psychological flexibility	.43**	-.64**	-.55**	-.31**	-.53**	.48**	.30**	.37**	-.60**	1

Note. CR = Care Recipient

*Correlation is significant at the .05 level (2-tailed), **Correlation is significant at the .01 level (2-tailed).

Multivariate Analysis

Prediction of Depressive Symptoms

Table 1.4 presents the results of the hierarchical multiple regression analysis testing the predictive power of variables on depression. The final model included eight variables and accounted for 50% of the variance in depression (Adj. $R^2 = .50$), which was highly significant ($F_{[8, 135]} = 18.58, p < .001$) and represented a large effect size ($f^2 = 1.0$). Avoidant coping ($\beta = .18, p < .05$) and psychological flexibility ($\beta = -.37, p < .001$) were the only remaining significant predictors in the final model. The age of the care-recipient ($\beta = .12, p = .056, ns$) and the functional disability of the care-recipient ($\beta = .14, p = .057, ns$) approached significance.

Prediction of Symptoms of Anxiety

For anxiety, the final model included five variables and accounted for 35% of the variance ($\text{Adj. } R^2 = .35$), which was highly significant ($F_{[5, 138]} = 16.29, p < .001$), and represented a large effect size ($f^2 = .54$). Functional disability ($\beta = .27, p = .001$), avoidant coping ($\beta = .22, p < .05$) and psychological flexibility ($\beta = -.38, p < .001$) were all significant predictors in the final model (Table 1.5).

Prediction of Satisfaction of Life

The final model for satisfaction with life included eight variables and accounted for 53% of the variance ($\text{Adj. } R^2 = .53$), which was highly significant ($F_{[8, 135]} = 21.40, p < .001$) and demonstrated a large effect size ($f^2 = 1.14$) (Table 1.6). Functional disability ($\beta = -.18, p < .01$), perceived burden ($\beta = -.34, p < .001$) and problem-focused coping ($\beta = .17, p < .01$) were all significant predictors in the final model. Of the three covariates, time spent caring ($\beta = -.19, p < .01$) and age of the caregiver ($\beta = -.19, p < .01$) remained significant in the final model. The addition of psychological flexibility in step four of the regression did not significantly increase the overall predictive variance of the model ($\Delta R^2 = .01, p = .129, ns$).

Table 1.4 Hierarchical Regression Analysis of Depression

Step	Variables	β	t	p	R^2	Adj. R^2	ΔR^2	Δp	$F_{(k,143-k)}$	p	f^2
1					.08	.07	.08	.006	4.30	.006	0.08
	Time caring ^a	.19	2.33	.021							
	Additional caregivers ^b	.12	1.37	.174							
	Care-recipient age	.13	1.56	.122							
2					.36	.33	.28	<.001	12.98	<.001	0.49
	Time caring	-.00	-0.05	.964							
	Additional caregivers	.03	0.35	.727							
	Care-recipient age	.07	0.99	.327							
	Functional disability	.16	1.94	.054							
	Perceived burden	.31	3.36	.001							
	Social support	-.24	-2.80	.006							
3					.46	.43	.10	<.001	16.44	<.001	0.75
	Time caring	.02	0.26	.795							
	Additional caregivers	-.00	-0.05	.959							
	Care-recipient age	.11	1.55	.123							
	Functional disability	.21	2.70	.008							
	Perceived burden	.17	1.82	.071							
	Social support	-.21	-2.62	.010							
	Avoidant coping	.35	4.91	<.001							
4					.52	.50	.07	<.001	18.58	<.001	1.0
	Time caring	.05	0.74	.463							
	Additional caregivers	-.01	-0.21	.833							
	Care-recipient age	.12	1.92	.056							
	Functional disability	.14	1.92	.057							
	Perceived burden	.11	1.22	.223							
	Social support	-.12	-1.59	.114							
	Avoidant coping	.18	2.30	.023							
	Psychological flexibility	-.37	-4.32	<.001							

Note. β = standardised beta; R^2 = R square; ΔR^2 = R square change; k = number of predictors

a = Time caring was coded 0 = <12h daily, 1 = >12h; b = Additional caregivers was coded 0 = no additional caregivers,

1 = additional caregivers

Table 1.5 Hierarchical Regression Analysis of Anxiety

Step	Variables	β	t	p	R^2	Adj. R^2	ΔR^2	Δp	$F_{(k,143-k)}$	p	f^2
1					0.18	0.16	0.18	<.001	9.88	<.001	0.19
	Functional disability	.26	2.98	.003							
	Social support	-.15	-1.55	.124							
	Perceived burden	.12	1.19	.237							
2					0.30	0.28	0.13	<.001	15.01	<.001	0.39
	Functional disability	.33	4.01	<.001							
	Social support	-.11	-1.24	.219							
	Perceived burden	-.04	-0.44	.659							
	Avoidant coping	.40	5.03	<.001							
3					0.37	0.35	0.07	<.001	16.29	<.001	0.54
	Functional disability	.27	3.42	.001							
	Social support	-.03	-0.29	.772							
	Perceived burden	-.10	-1.05	.297							
	Avoidant coping	.22	2.50	.014							
	Psychological flexibility	-.38	-3.91	<.001							

Note. β = standardised beta; R^2 = R square; ΔR^2 = R square change; k = number of predictors

Table 1.6 Hierarchical Regression Analysis of Satisfaction with Life

Step	Variables	β	t	p	R^2	Adj. R^2	ΔR^2	Δp	$F_{(k,143-k)}$	p	f^2
1					.24	.22	.24	<.001	14.63	<.001	0.28
	Time caring ^a	-.36	-4.87	<.001							
	Age	-.20	-2.49	.014							
	Care-recipient age	-.14	-1.81	.073							
2					.52	.50	.28	<.001	24.89	<.001	1.0
	Time caring	-.17	-2.65	.009							
	Age	-.19	-3.00	.004							
	Care-recipient age	-.05	-0.82	.416							
	Functional disability	-.20	-2.83	.005							
	Perceived burden	-.37	-4.59	<.001							
	Social support	.14	1.87	.064							
3					.55	.53	.03	.003	23.89	<.001	1.12
	Time caring	-.18	-2.78	.006							
	Age	-.19	-3.04	.003							
	Care-recipient age	-.08	-1.26	.209							
	Functional disability	-.18	-2.73	.007							
	Perceived burden	-.38	-4.92	<.001							
	Social support	.07	0.93	.355							
	Problem- focused coping	.19	3.01	.003							
4					.56	.53	.01	.129	21.40	<.001	1.14
	Time caring	-.19	-2.94	.004							
	Age	-.19	-3.17	.002							
	Care-recipient age	-.08	-1.31	.190							
	Functional disability	-.18	-2.60	.010							
	Perceived burden	-.34	-4.15	<.001							
	Social support	.04	0.58	.561							
	Problem- focused coping	.17	2.65	.009							
	Psychological flexibility	.11	1.53	.129							

Note. β = standardised beta; R^2 = R square; ΔR^2 = R square change; k = number of predictors

a = Time caring was coded 0 = <12h, 1 = >12h

Conditional Process Analysis

Figures 1.1 to 1.3 depict diagrams of the theoretical models that were tested on each outcome (i.e. depression, anxiety and satisfaction with life) using conditional process analysis. These specific models were selected apriori after synthesising and considering previous theoretical accounts of the predictors, outcomes and their relationships. According to the SPM, appraisal (i.e. perceived burden) would have a mediating role between

caregiver stressors (functional disability) and outcomes, tested in the mediation models in Figure 1.1a, 1.2a and 1.3a. Negative appraisals are common and reoccurring for caregivers. Social support, effective coping or greater level of psychological flexibility were predicted to lessen the influence of appraisals (i.e. perceived burden), tested by the moderated mediation models.

In each diagram, numbers on the line represent beta coefficients (unstandardised) and only significant paths are presented for clarity. The total variance for each model is presented below the diagram together with a table describing the regression coefficients onto the dependent variable in each model. The boxes on indirect paths represents the indirect effect at levels of the moderator, shown at low ($-1 SD$), mean and high ($+1 SD$). All boot-strapped confidence intervals are of 5000 resamples.

Depression as Dependent Variable

Figure 1.1a presents the mediation model used to explore if the relationship between functional disability of the care-recipient and caregiver depression is mediated by perceived burden, as theorised from the SPM. The total model accounted for 32% of the variance in depression, which was significant ($R^2 = .32, p < .001$). Functional disability did not have a direct impact on depression, but there was an indirect effect via perceived burden ($b = .06$, 95% LLCI = .03, ULCI = .09). This suggests that the level of functional disability of a person with ABI is associated with caregiver depression only via the caregiver's appraisal (i.e. perceived burden), in line with the SPM.

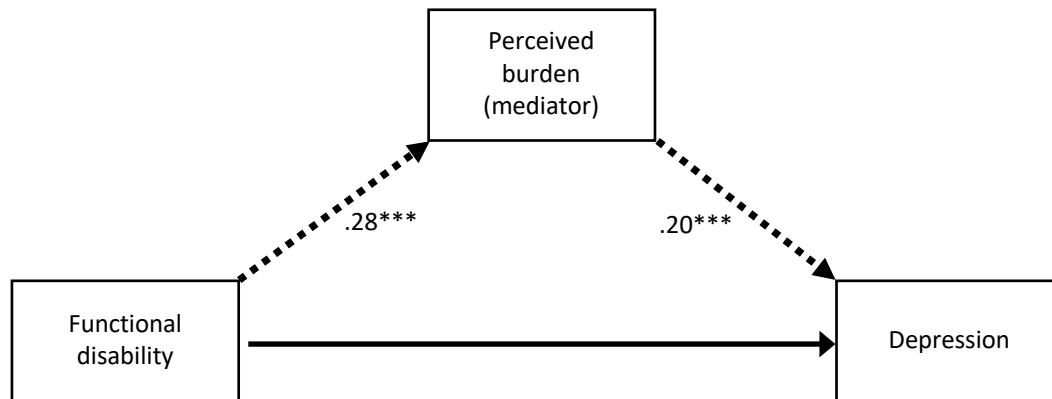
Figures 1.1b to 1.1d represent the models in which avoidant coping, social support and psychological flexibility were explored as moderators of the mediated path between functional disability and depression, via perceived burden. In model 1.1b and 1.1c, there was no moderating effect of avoidant coping or social support, and the mediating path

between disability and depression via perceived burden remained significant. Interestingly, when avoidant coping (Figure 1.1b) was tested as a moderator, the indirect path between functional disability and depression became significant. This could be due to avoidant coping being a stronger direct predictor of depression than perceived burden, which could have suppressed the indirect path and allowed the direct effect to become significant.

In model 1.1d, psychological flexibility was found to significantly moderate the influence of perceived burden ($b = -.002, p < .05$). At high levels of psychological flexibility, perceived burden was no longer a significant predictor of depression ($b = .05, p = .193, ns$), and no longer mediated the path between disability and caregiver depression ($b = .01, 95\% \text{ LLCI} = -.01, \text{ULCI} = .03$). This suggests that psychological flexibility acts as a buffer against the indirect impact of negative appraisals (i.e. perceived burden) on caregiver depression.

Figure 1.1 Conditional Process Analysis Models with Depression as Dependent Variable

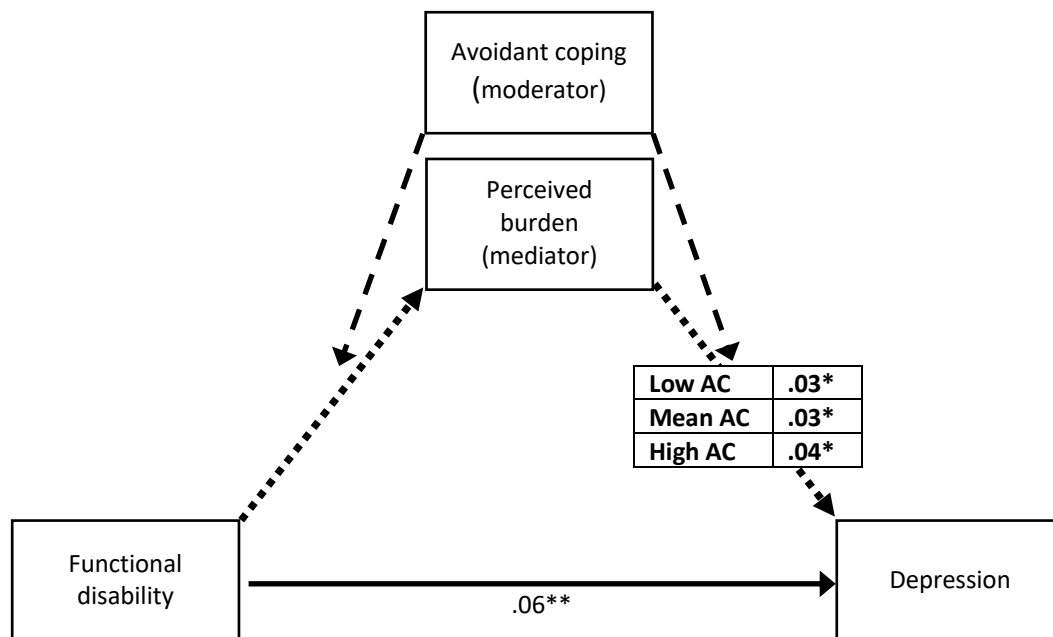
a)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.1a

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.04	-.001	.09	.054, <i>ns</i>
Perceived burden	.20	.13	.27	<.001
CR age (covariate)	.03	-.20	.08	.226, <i>ns</i>
Indirect path of mediator	.06	.03	.09	<.05
Total model: $R^2 = .32$, $p < .0001$, $f^2 = .47$				

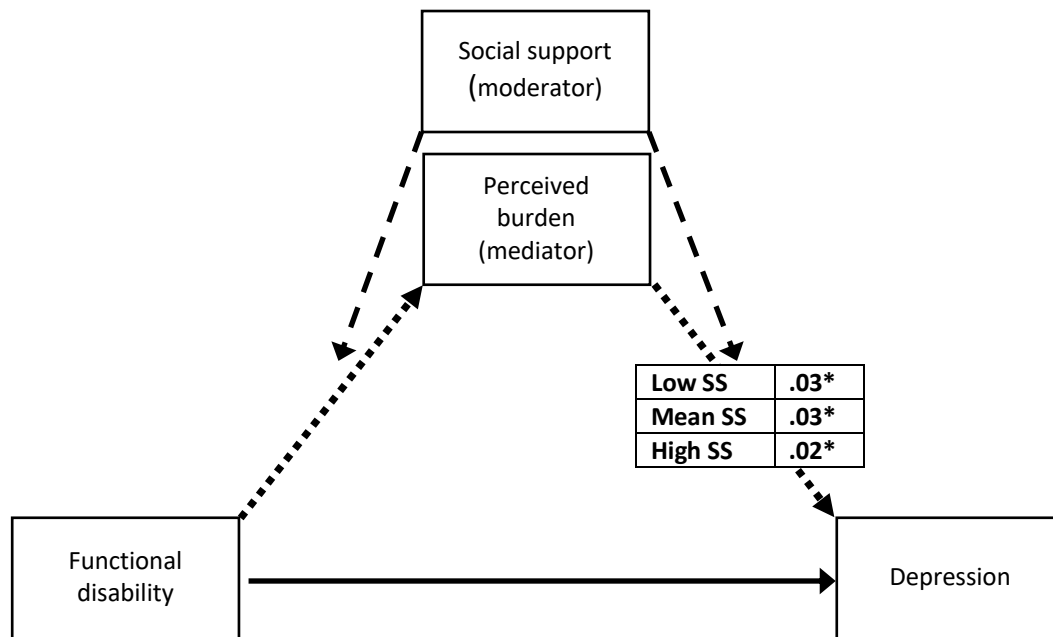
b)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.1b

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.06	.02	.09	.004
Perceived burden	.04	-.20	.28	.759, <i>ns</i>
Avoidant coping	.19	-.34	.72	.473, <i>ns</i>
Burden x avoidant coping	.004	-.01	.01	.470, <i>ns</i>
CR age (covariate)	.04	.10	-.01	.102, <i>ns</i>
Total model: $R^2 = .43$, $p < .0001$, $f^2 = .75$				

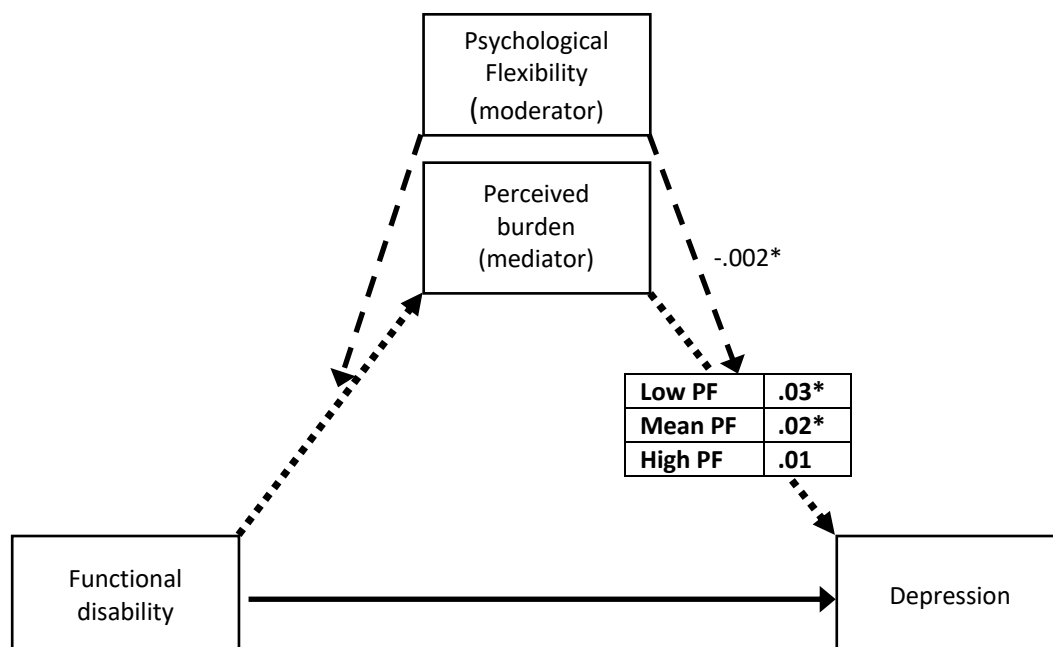
c)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.1c

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.04	-.002	.08	.059, <i>ns</i>
Perceived burden	.27	.03	.50	.028
Social support	.05	-.32	.41	.800, <i>ns</i>
Burden x social support	-.004	-.01	.003	.260, <i>ns</i>
CR age (covariate)	.03	-.02	.08	.275, <i>ns</i>
Total model: $R^2 = .37$, $p < .0001$, $f^2 = .59$				

d)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.1d

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.03	-.004	.07	.080, <i>ns</i>
Perceived burden	.27	.10	.43	.002
Psychological flexibility	-.01	-.12	.10	.819, <i>ns</i>

Burden x psychological flexibility	-.002	-.004	-.0004	.021
CR age (covariate)	.04	-.002	.09	.064, <i>ns</i>
Total model: $R^2 = .51, p < .0001, f^2 = 1.04$				

Key:  Direct path  Indirect path  Moderator

* $p < .05$ ** $p < .01$ *** $p < .001$; BCI = Bootstrapped confidence interval; LL = Lower Limit;

UL = Upper Limit; CR = Care-recipient; AC = Avoidant coping; SS = Social support; PF =

Psychological flexibility

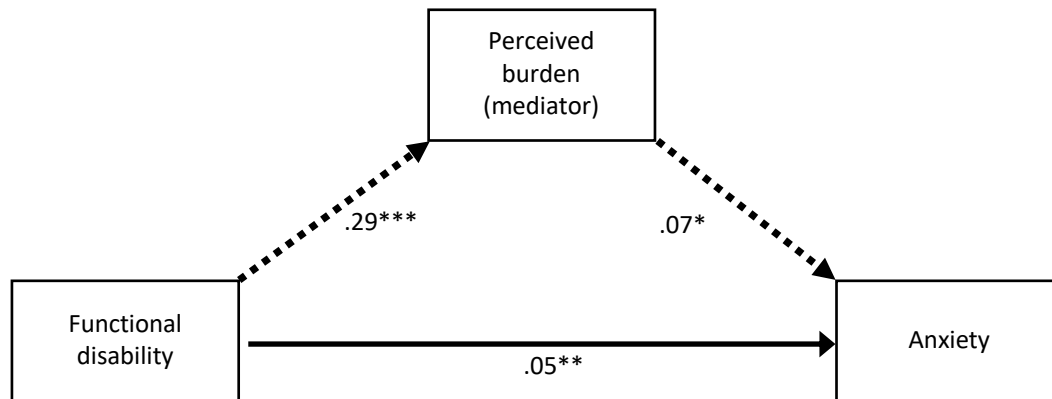
Anxiety as Dependent Variable

The total mediation model in Figure 1.2a accounted for 16% of the variance in anxiety, which was significant ($R^2 = .16, p < .001$). Functional disability had a direct influence on anxiety ($b = .05, p < .01$). Perceived burden mediated the path between disability and anxiety ($b = .02, 95\% \text{ LLCI} = .004, \text{ ULCI} = .004$). As such, the disability of the care-recipient was associated with the level of anxiety amongst caregivers directly, and via their appraisal of the caregiving situation (i.e. perceived burden).

In the moderated mediation models depicted in Figures 1.2b to 1.2d, no significant moderating role of avoidant coping, social support or psychological flexibility was demonstrated. Surprisingly, the indirect path between functional disability and anxiety, via perceived burden, became non-significant whilst the direct paths between functional disability and anxiety remained significant for all three moderated mediation models (i.e. Figure 1.2b-d).

Figure 1.2 Conditional Process Analysis Models with Anxiety as Dependent Variable

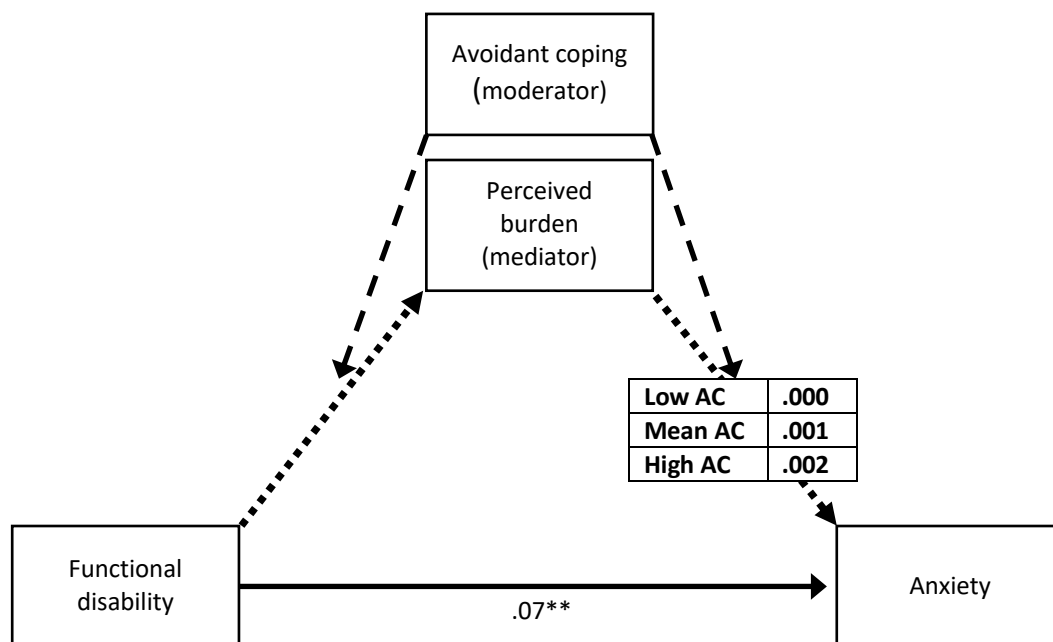
a)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.2a

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.05	.02	.09	.004
Perceived burden	.07	.01	.13	.020
Indirect path via mediator	.02	.004	.04	<.05
Total model: $R^2 = .16$, $p < .0001$, $f^2 = .19$				

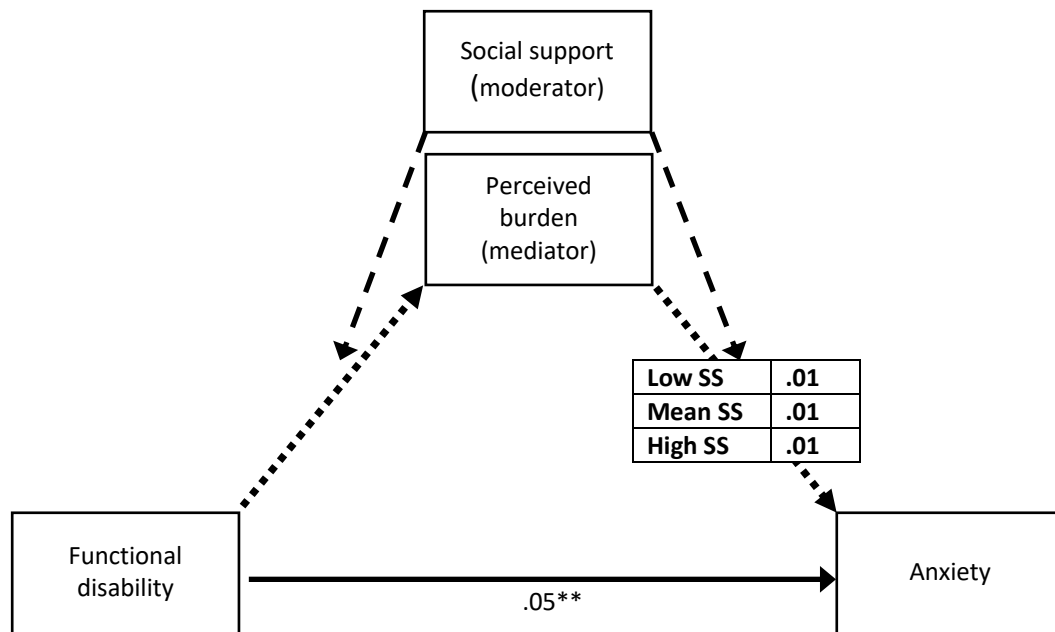
b)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.2b

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.07	.03	.10	<.001
Perceived burden	-.01	-.21	.19	.925, <i>ns</i>
Avoidant coping	.29	-.16	.73	.200, <i>ns</i>
Burden x avoidant coping	.001	-.01	.01	.885, <i>ns</i>
Total model: $R^2 = .29$, $p < .0001$, $f^2 = .41$				

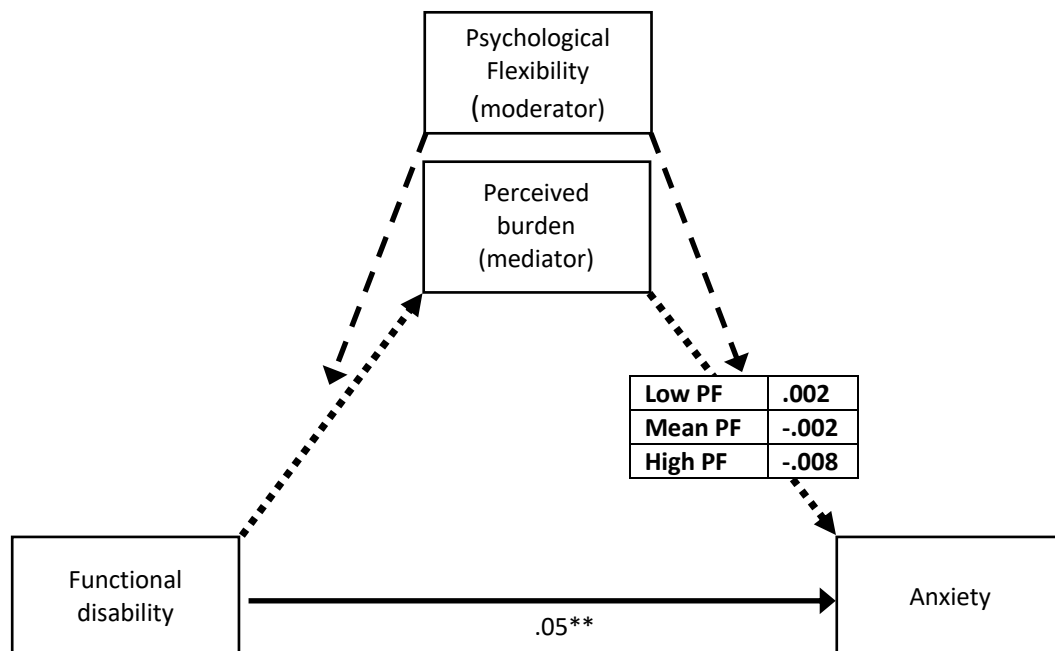
c)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.2c

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.05	.02	.09	.004
Perceived burden	.05	-.18	.23	.804, <i>ns</i>
Social support	-.09	-.41	.22	.561, <i>ns</i>
Burden x social support	.001	-.01	.01	.877, <i>ns</i>
Total model: $R^2 = .17$, $p < .0001$, $f^2 = .20$				

d)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.2d

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	.05	.02	.08	.005
Perceived burden	.06	-.08	.21	.376, <i>ns</i>
Psychological flexibility	-.05	-.14	.05	.313, <i>ns</i>
Burden x psychological flexibility	-.001	-.003	.001	.229, <i>ns</i>

Total model: $R^2 = .35, p < .0001, f^2 = .54$

Key:  Direct path  Indirect path  moderator

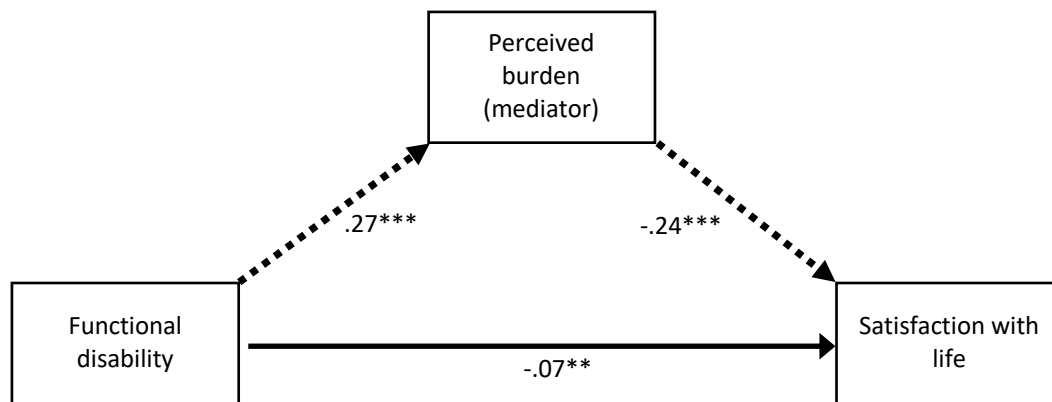
* $p < .05$ ** $p < .01$ *** $p < .001$; BCI = Bootstrapped confidence interval; LL = Lower Limit;

UL = Upper Limit; AC = Avoidant coping; SS = Social support; PF = Psychological flexibility

Satisfaction with Life as Dependent Variable

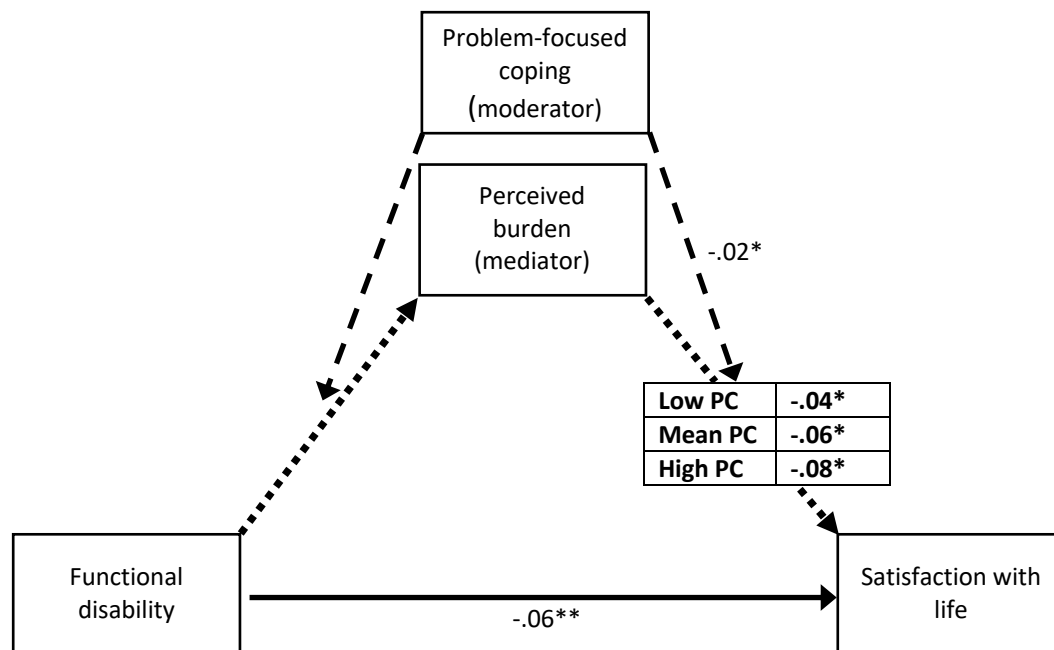
The mediation model (Figure 1.3a) accounted for 51% of the variance in satisfaction of life, which was highly significant ($R^2 = .51, p < .001$). Functional disability directly influenced satisfaction with life ($b = -.07, p < .01$). Functional disability was also associated with worse life satisfaction indirectly via perceived burden ($b = -.07, 95\% \text{ LLCI} = -.10, \text{ULCI} = -.04$).

In Figure 1.3b, the indirect path between functional disability and satisfaction with life, via perceived burden, remained significant. The model depicted in Figure 1.3b demonstrates a moderating effect of problem-focused coping on the influence of perceived burden ($b = -.02, p < .05$). Surprisingly, the direct and indirect influence of perceived burden on satisfaction with life increased with problem-focused coping. Higher reported frequency of problem-coping strategies (e.g. taking action, seeking advice, problem-solving) strengthened the influence of cognitive appraisals (i.e. perceived burden) on satisfaction with life. In model 3c and 3d, there were no moderating effects of social support or psychological flexibility, and the indirect path between disability and satisfaction with life, via perceived burden, remained significant in both models. Both covariates (time caring, age of caregiver) remained significant predictors of satisfaction with life in all four models depicted in Figure 1.3.

Figure 1.3 Conditional Process Analysis Models with Satisfaction of Life as Dependent**Variable****a)**

Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.3a

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	-.07	-.11	-.02	.007
Perceived burden	-.24	-.32	-.17	<.001
Age (covariate)	-.12	-.19	-.05	.001
Time caring (covariate)	-2.84	-4.75	-.92	.004
Indirect path via mediator:	-.07	-.10	-.04	<.05

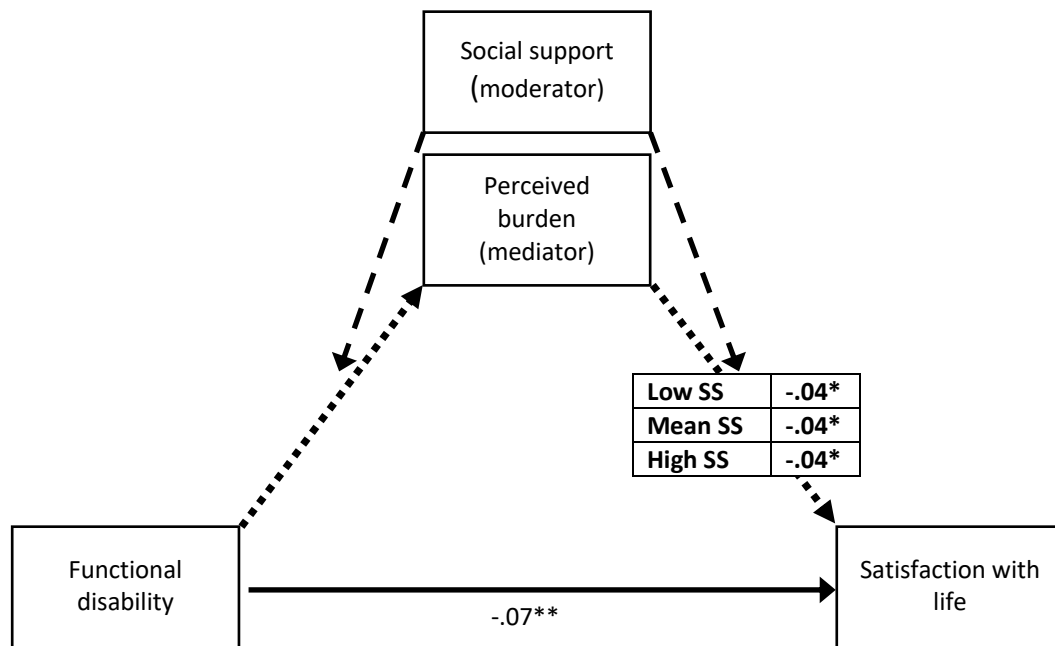
Total model: $R^2 = .51$, $p < .0001$, $f^2 = 1.04$ **b)**

Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.3b

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	-.06	-.11	-.02	.005
Perceived burden	.11	-.17	.38	.437, <i>ns</i>
Problem-focused coping	1.40	.56	2.24	.001
Burden x problem coping	-.02	-.04	-.01	.012
Age (covariate)	-.14	-.20	-.07	<.001
Time caring (covariate)	-3.07	-4.91	-1.24	.001

Total model: $R^2 = .56$, $p < .0001$, $f^2 = 1.27$

c)

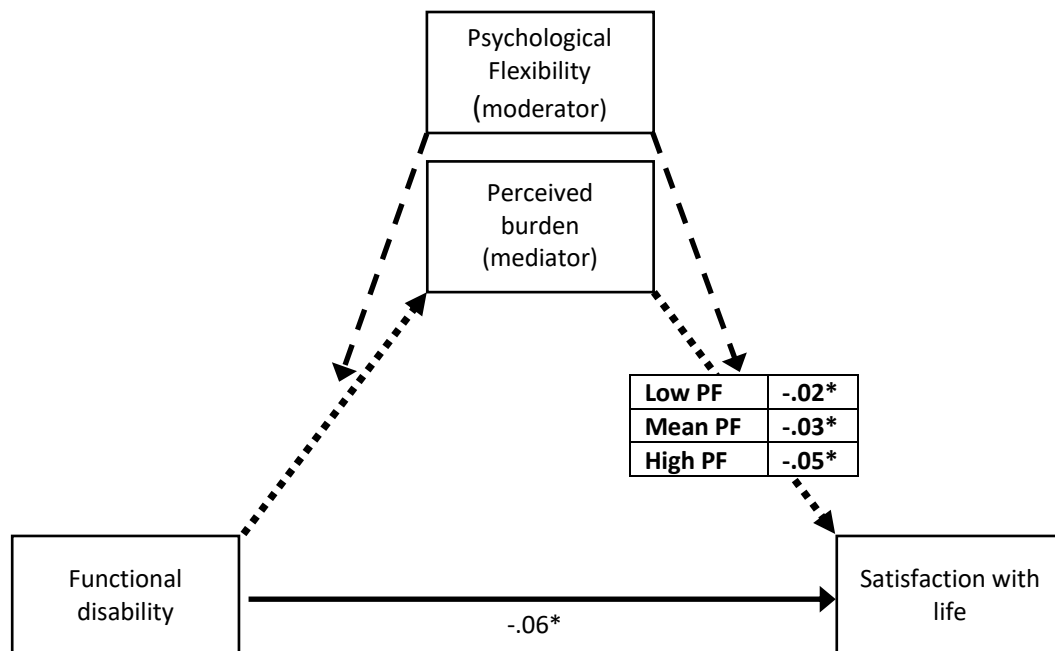


Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.3c

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
Functional disability	-.07	-.11	-.02	.006
Perceived burden	-.25	-.50	.01	.058, <i>ns</i>
Social support	.04	-.36	.43	.854, <i>ns</i>
Burden x social support	.001	-.01	.01	.716, <i>ns</i>
Age (covariate)	-.12	-.19	-.05	.001
Time caring (covariate)	-2.52	-4.45	-.53	.011

Total model: $R^2 = .52$, $p < .0001$, $f^2 = 1.08$

d)



Unstandardised regression coefficients and bootstrapped confidence intervals for the model in Figure 1.3d

	<i>b</i>	LL BCI	UL BCI	<i>p</i>
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Functional disability	-.06	-.11	-.01	.011
Perceived burden	-.09	-.29	.11	.378, <i>ns</i>
Psychological flexibility	.13	-.004	.26	.057, <i>ns</i>
Burden x psychological flexibility	-.001	-.004	.001	.255, <i>ns</i>
Age (covariate)	-.13	-.20	-.06	<.001
Time caring (covariate)	-3.04	-4.93	-1.16	.002
Total model: $R^2 = .53$, $p < .0001$, $f^2 = 1.13$				

Key:  Direct path  Indirect path  moderator

* $p < .05$ ** $p < .01$ *** $p < .001$; BCI = Bootstrapped confidence interval; LL = Lower Limit;

UL = Upper Limit; PC = Problem-focused coping; SS = Social support; PF = Psychological flexibility

Discussion

This study investigated the role of psychological flexibility amongst caregivers of adults with ABI. The aim was to examine the relative strength of psychological flexibility, and its specific role, in explaining caregiver outcomes compared to established constructs. Functional disability of the care-recipient, perceived burden, coping, social support and psychological flexibility were all explored as predictors of depression, anxiety and satisfaction with life.

Psychological Flexibility

As predicted, large negative correlations were observed between psychological flexibility and depression and anxiety, whilst a moderate positive correlation with satisfaction with life was found. Psychological flexibility was the strongest predictor of both depression and anxiety in the final regression models, when established constructs had been accounted for. This finding is in line with studies on caregivers of other conditions, such as dementia and psychosis (Jansen et al., 2017; Kishita, Contreras, West, & Mioshi, 2020). The present study is the first to establish psychological flexibility as a significant

predictor of depression and anxiety in caregivers of adults with ABI. In contrast to hypothesis; psychological flexibility was not a significant predictor of satisfaction of life.

The conditional process analysis suggests that the functional disability of the care-recipient is only associated with levels of caregiver depression indirectly via the caregiver's negative appraisal of burden (i.e. perceived burden), in line with the SPM. This indirect path was moderated by psychological flexibility, suggesting a buffering role. The effect of negative appraisals was diminished, and even became non-significant, with higher levels of psychological flexibility. This finding was in line with predictions, and in accordance with psychological flexibility theory. Caregivers who reported higher levels of psychological flexibility may be able to take an observing and flexible stance towards their inner experiences (e.g. negative appraisals) and challenging circumstances. This finding is particularly relevant for the caregiver population as negative appraisals and difficult thoughts are common, and to some extent expected in this challenging context, and therefore a difficult target for change (Márquez-González et al., 2013). Psychological flexibility was not found to have a moderating role for anxiety or satisfaction with life.

The Stress Process Model

The present study demonstrated medium to large correlations between perceived burden and outcomes in predicted directions. Perceived burden was the strongest predictor of variance in satisfaction with life but was not a significant predictor in regression models of depression or anxiety. As hypothesised, perceived burden mediated the direct path between disability of the care-recipient and all three outcomes in simple mediation models (i.e. Figure 1.1a, 1.2a and 1.3a). The mediating role of caregiver appraisals is in accordance with previous findings (Chronister et al., 2016; Harris et al., 2001). However, the strength of these associations diminished when other constructs were included in the models, to the

extent that the indirect path between disability and anxiety via perceived burden became non-significant. A limitation of previous research is that appraisals are compared to concepts from within the SPM, but rarely to external theoretical frameworks. The results of the present study suggest that negative appraisals are important for life satisfaction amongst caregivers, but less fundamental than expected for depression and anxiety, for which psychological flexibility may be a stronger influence.

Social support and coping were predicted to buffer the impact of appraisal on distress and satisfaction with life. Social support correlated with outcomes in expected directions, but it was not a significant independent predictor of variance of any outcome, or a moderator in conditional process analyses. These results suggest that social support is an important factor on its own, consistent with previous research (Chronister et al., 2016; Ergh et al., 2002). However, social support had a comparatively weaker influence on distress and satisfaction with life when psychological flexibility and the additional constructs from the SPM were accounted for.

Consistent with theory, avoidant coping was a significant predictor of anxiety and depression. Contrary to predictions, avoidant coping was not a moderator of appraisals. Interestingly, when avoidant coping was entered into the moderated mediation model functional disability had a significant direct influence on depression, although this relationship was non-significant in the simple mediation model. It appears that avoidant coping suppressed the influence of perceived burden as an indirect source of variance, allowing the direct path to emerge as significant.

This finding indicates that avoidant coping is more strongly associated with depression than cognitive appraisal (i.e. perceived burden), as is evident from the results of the regression analysis. Experiential avoidance has previously been found to be a strong

predictor of depression amongst caregivers of people with dementia (Losada, Márquez-González, Romero-Moreno, & López, 2014; Spira et al., 2007). The adverse influence of avoidant strategies is consistent with behavioural theory and intervention, such as the psychological flexibility model and ACT in which reducing experiential avoidance is a fundamental process (Hayes, Strosahl, & Wilson, 2012).

Another interesting finding was that problem-focused coping positively moderated the mediation effect of appraisals on satisfaction with life. Although somewhat counterintuitive, problem-focused coping has been found to have a negative relationship with wellbeing in previous research (Chronister et al., 2010; Kendall & Terry, 2008). Chronister and colleagues (2010) found that problem-focused coping was significantly correlated with worse QoL. It has been hypothesised that a high level of problem-solving coping could suggest difficulties with acceptance and adjustment (Chronister et al., 2010; Cooper, Katona, Orrell, & Livingston, 2008).

The present study did not find a direct negative correlation between problem-focused coping and satisfaction of life. However, the current results indicate that negative appraisals had a stronger influence on satisfaction of life as problem-focused coping increased. Problem-solving and active approaches aimed at changing a difficult situation may not be workable strategies for all caregivers in the long-term, as many challenges associated with caregiving are ongoing and unremitting. Negative appraisals could therefore potentially have a stronger indirect influence on the satisfaction of life amongst caregivers who more rigidly adhere to a problem-solving agenda. However, it is also possible that caregivers who are dissatisfied with life and report stronger negative appraisals tend to use more problem-focused strategies.

Implications for Practice

The findings from the present study suggest that psychological flexibility, negative appraisals and avoidance strategies could be potential modifiable targets for interventions aiming to help caregivers adjust and improve their wellbeing. Acceptance and Commitment Therapy (ACT) would be a suitable intervention as it aims to increase psychological flexibility and to reduce experiential avoidance (Hayes, Strosahl, & Wilson, 2012). ACT-based interventions could offer strategies to increase awareness of appraisals and to relate more openly and self-compassionately to difficult thoughts and emotions. Caregivers may also benefit from a strengthened connection to values intrinsic in providing care to someone, and to broaden their own activities and self-care repertoire that often is reduced or put on hold. A more traditional cognitive behavioural approach (e.g. Beck, 1976) could target appraisals and avoidant strategies with cognitive restructuring and behavioural activation. Research on caregivers of people with dementia has indicated that both ACT and CBT are efficacious (Losada et al., 2015).

In addition to being the first study exploring psychological flexibility in this population, the present results are also the first to support the SPM amongst caregivers across a wider range of ABIs. It is hoped that by presenting data across aetiologies this will benefit a broad population of caregivers and inform services attended by patients suffering from a wide range of ABIs. Notwithstanding, the decision to include and analyse caregivers of all types of ABI led to a somewhat heterogeneous sample, which could have implications. Whilst increased heterogeneity can improve the generalisability of the results, it will undoubtedly introduce a larger degree of error in the data. This greater degree of error could impact on the validity and reliability of these findings.

Limitations

Several limitations of the present study should be considered. The design was cross-sectional and correlational and casual relationships cannot be inferred from the results. The use of convenience sampling through an online survey advertised via brain injury organisations reduces the generalisability of the data to other caregivers who may not have access to these supportive charities or the internet. Similarly, all participants were self-selecting and may not be representative of the caregiver population. All data were collected using self-report measures, which can lead to common response biases and issues of validity, such as social desirability or strong influence of contextual factors. The use of an online survey and highlighting that responses were completely anonymous may have reduced social desirability bias. Attempts were made to reduce biases from difficulties with interpretation or comprehension of instructions, such as using large fonts and non-technical language.

No subgroup analyses on specific groups of participants were undertaken in the present study. As certain ABIs were more predominant in the present sample, this raises the question of how representative the findings are to carers of specific ABIs. For example, infectious ABIs were the most common ABI in the present sample, closely followed by stroke and TBI. There were less caregivers from aetiologies such as anoxic injury or aneurisms, and these specific groups are less represented in the current sample.

In accordance with the SPM, caregiver appraisals were defined and measured as perceived burden. Additional aspects of the appraisal concept, such as mastery and satisfaction, were not measured. The rationale for this decision was to minimise the overall response burden on participants. A conscious effort was made to use brief questionnaires and limit variables to the most relevant for the study's aims. However, by doing so the study may have overlooked the many positive aspects of caregiving that are reported in the

literature which undoubtedly play an important role for wellbeing and adjustment (Cohen et al., 2002). Time spent caring was one of the demographic factors found be associated with satisfaction of life. This variable was measured categorically and is susceptible to ceiling effects.

Lastly, recruitment to this study took place during the COVID-19 pandemic. Participating caregivers were living under extraordinary circumstances including societal lockdowns and with increased uncertainty and caregiving responsibilities. It could be argued that these circumstances potentially limit the generalisability of our findings further. Table 1.2 includes comparative data on the DASS21 from a study recruiting prior to the COVID-19 pandemic. Slightly higher mean level anxiety and depression is observed in the present sample, although it is difficult to speculate in what direction this could impact on our data.

Future directions

Future research should replicate the current findings using longitudinal or controlled treatment designs to establish causality. Both positive and negative appraisals of caregiving are recommended to be included in future designs in order to capture this construct fully. Caregiving is a multifactorial and heterogeneous concept and future research would benefit from larger samples that can be analysed using structural equational modelling to allow for several dependent variables simultaneously. The current study provides useful data for estimations of effect sizes and sample sizes required for future studies. The present study did not find any significant differences on outcomes between caregivers of different types of brain injuries. Future studies are encouraged to continue to include a variety of ABI conditions.

Conclusion

Compared to established constructs from the SPM, psychological flexibility was found to be the strongest factor in explaining variance in anxiety and depression amongst caregivers of adults with ABI. Psychological flexibility was found to moderate the effect of caregiver appraisal on depression. Caregiver appraisals were the strongest predictor for satisfaction of life and mediated the relation between levels of care-recipient functional disability and caregiver outcomes.

The findings of this study have added to the SPM, and to our understanding of caregiver distress and wellbeing. As in many other populations, psychological flexibility appears to play a central role for outcomes amongst caregivers of adults with ABI, and further exploration into this area is warranted.

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Following Stage of the Thesis

The results of the cross-sectional study in the first chapter illustrate the key role that constructs, such as psychological flexibility and appraisals, play in the wellbeing of caregivers of adults with ABI. These factors would be suitable targets for interventions due to the potential to modify them in order to alleviate distress and improve wellbeing. However, there is a consensus that there is inadequate access to interventions for this population, preventing their emotional needs from being met (Gan, Gargaro, Brandys, Gerber, & Boschen, 2010; Lincoln et al., 2011; Murray, Maslany, & Jeffery, 2006).

There are several potential reasons for why interventions to support caregivers are not routinely offered or accessed. From a service perspective, the focus can be on the person with the brain injury and clinicians are not always able to allocate time or resources to support carers. Caregivers, on the other hand, report being unable to take time off caring or to travel to appointments. New ways of delivering support have been suggested in order to overcome some of these barriers and to improve access to services.

The second chapter of this thesis will therefore explore the research on supportive interventions for caregivers of adults with ABI that are delivered remotely. This will be done by conducting a systematic review to synthesise existing studies on remotely delivered interventions designed to improve the wellbeing of caregivers of adults with ABI.

Chapter two

Remotely Delivered Interventions for Caregivers of Adults with Acquired Brain Injuries:

a Systematic Review

Title Page*

Title: Remotely Delivered Interventions for Caregivers of Adults with Acquired Brain Injuries:
a Systematic Review

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Abstract

There is a need for improved access to interventions supporting the wellbeing of caregivers of adults with ABI. There are various barriers to services, and remotely delivered interventions could improve access to evidence-based support interventions for this population. The present review sought to synthesise studies evaluating any type of remotely delivered intervention designed to improve the wellbeing of caregivers of adults with an ABI, and to comment on the methodological quality of this research. Systematic searches were conducted on Embase, MEDLINE, PsychINFO, Psych Articles, NeuroBITE and the grey literature up until February 2021. RCTs were appraised in terms of methodological quality using the PEDroP tool. A total of twelve studies (10 RCTs, 1 pre-post, 1 case-series) meeting inclusion criteria were identified. The methodological quality was generally adequate. Interventions were delivered over the telephone, online, via videoconferencing and by written information, and evaluated on a wide range of wellbeing outcomes. The majority of studies evaluated an intervention for caregivers of people with stroke. Albeit limited, promising findings were identified on primary and secondary wellbeing outcomes. General statements on the efficacy of remote delivery for ABI carers are premature, and specific recommendations are provided for future research.

Introduction

Informal caregivers function as extensions to the health care system but without formal training, adequate financial support or routine access to health care services (Ramkumar & Elliott, 2010; Shewchuk & Elliott, 2000). Often defined as “hidden patients” (Roche, 2009), it is well documented that caregivers are at higher risk of developing physical and mental health problems when compared to the general population (Adelman, Tmanova, Delgado, Dion, & Lachs, 2014; Pinguart & Sörensen, 2003; Vitaliano, Zhang, & Scanlan, 2003).

Acquired Brain Injury (ABI) is a collective term referring to an injury or illness resulting in damage to the brain, which occurred after birth. Traumatic Brain Injury (TBI), strokes, brain tumours, infectious diseases or hypoxic injuries are all examples of ABIs. Although each type of ABI can have a distinct aetiology and varying sequelae, they can all have a devastating impact on the survivor, their loved ones and families (Jackson et al., 2009). ABI can lead to significant impairment in functioning, and recovery varies greatly between individuals. In many cases the injury results in lifelong disability with the person requiring support and assistance with activities of daily living (Denham et al., 2020). After leaving hospital the majority of this support comes from family and friends, who become informal caregivers assisting with, for example, financial, social, emotional and recreational support needs.

Supporting a loved one through their brain injury rehabilitation process and beyond can be rewarding, and caregiving can be a valued role in someone’s life (MacKenzie & Greenwood, 2012; Pierce, Steiner, Govoni, Thompson, & Friedemann, 2007). Notwithstanding, research has also found that psychological distress, burden and reduced quality of life is common among caregivers of adults with ABI and that these difficulties

often persist over time (Denham et al., 2020; Kreutzer, Rapport, et al., 2009; Ponsford & Schönberger, 2010; Sterckx et al., 2013). Moreover, links between caregiver distress and the wellbeing and functioning of the person with the ABI have been demonstrated, which will have direct negative impact on the rehabilitation process (Low, Payne, & Roderick, 1999; Perrin, Heesacker, Stidham, Rittman, & Gonzalez-Rothi, 2008; Pucciarelli et al., 2017). As the informal caregiver provides a vital system of support for people with ABI following discharge from hospital, their own wellbeing is paramount for a sustainable and holistic rehabilitation (Cattelani, Zettin, & Zoccolotti, 2010; Cicerone et al., 2011). Unfortunately, emotional support and sufficient information are two of the most commonly reported unmet needs of the caregiver following discharge from hospital (Murray et al., 2006).

Compared to other conditions, caring for an adult with ABI involves unique and specific challenges for the caregiver, which must be considered in order to meet the specific needs of this population. Compared to people providing care for someone with dementia, studies have found that ABI carers tend to be younger, more frequently living with the care-recipient, and generally reporting greater levels of burden (Harding et al., 2015; Jackson et al., 2009). The sudden onset of an ABI is a key distinction to dementia and other degenerative, progressive or developmental neurological conditions is (Lincoln et al., 2011). A sudden onset suggests that the caregiver does not have opportunity to adjust or prepare for their role. Moreover, degenerative and progressive neurological conditions such as dementia, Parkinson's disease or motor neuron disease have a declining course whilst ABI may involve improvements over time. Physical health conditions may have a sudden onset, but rarely involves the cognitive and behavioural consequences, or alterations in personality, that can be seen after ABI (Harding et al., 2015). Due to the unique

circumstances involved in caring for adults with ABI, there has been a call for research into interventions for this specific population (Lincoln et al., 2011).

Various types of interventions designed to support and improve the wellbeing amongst caregivers of people with ABI have been developed and evaluated with mixed findings (e.g. Boele et al., 2019; Boschen et al., 2007; Kreitzer et al., 2018). Interventions based solely on information provision, skills training or psychoeducation can improve practical skills, knowledge and potentially reduce burden, but are less effective in terms of psychological wellbeing such as depression, anxiety or quality of life (Forster et al., 2012; Shepherd-Banigan et al., 2018; Sörensen, Pinquart, & Duberstein, 2002).

In contrast, psychotherapeutic and counselling approaches target individual psychological difficulties and experiences of the caregiver in order to alleviate distress or improve wellbeing. Systematic reviews have highlighted that therapeutic and counselling approaches are promising in targeting psychological wellbeing of caregivers of adults with ABI, particularly when incorporated with skill- and knowledge-building interventions (Baker, Barker, Sampson, & Martin, 2017; Eldred & Sykes, 2008; Panzeri et al., 2019).

Why Remote Delivery is Promising for Caregivers

The need for supportive interventions to alleviate distress and improve wellbeing for caregivers of people with ABI is well documented. However, large gaps still exist in the provision of support for this group, and there are particular barriers to be addressed in order to improve access to services for this group.

From a service perspective, there are several potential reasons for why supportive and therapeutic caregiver interventions are not being offered routinely. Insufficient funding, a lack of resources and clinicians without the required training are all factors that need to be addressed to enable routine implementation of caregiving interventions (Sin et al., 2018).

Services also tend to focus on the person with the ABI, and the psychological needs of caregivers are given less priority (Bulsara & Fynn, 2006; Greenwood, MacKenzie, Harris, Fenton, & Cloud, 2011).

From the point of view of the caregiver, there are additional barriers to consider in order to improve access to services. Disruptions in areas such as employment and social life are common amongst caregivers as their caring role can take up much of their time (Ilse, Feys, de Wit, Putman, & de Weerd, 2008; Lou, Carstensen, Jørgensen, & Nielsen, 2017). As such, it is unsurprising that time constraints due to the nature of the caregiving role makes it difficult to access services that offer support. More time spent caring has also been associated with higher levels of caregiver stress suggesting that caregivers with the least time on their hands to engage with services might be the ones needing it the most (Forsberg-Wärleby et al., 2001; Smith et al., 2014). Greenwood (2010) and colleagues found that caregivers of people with stroke reported difficulties leaving the care-recipient for any longer periods due to uncertainty with regards to their safety and independence. These findings correspond with experiences of caregivers of other types of ABI and across age groups (Buschenfeld, Morris, & Lockwood, 2009; Sin et al., 2018). Recently, the effects of the global COVID-19 pandemic have left caregivers with additional barriers to access support and social networks, with the risk of an increased burden of care and more time spent caring.

Due to the many challenges and barriers that caregivers have to face when accessing services, supportive interventions delivered remotely are of particular interest for this population. Caregivers have reported that they would prefer flexible delivery methods that allow them to work around their caring commitments (Sin et al., 2018). As such, remote delivery offers an additional way for service providers to support caregivers.

Remotely Delivered Interventions

Although there has been a surge in developments due to the COVID-19 pandemic, the interest for remote delivery of psychological and supportive care interventions has grown steadily over the last two decades. Evidence now exists for a wide range of applications including psychological therapy for mental health problems (Andersson, Carlbring, Ljótsson, & Hedman, 2013; Cuijpers, Donker, Van Straten, Li, & Andersson, 2010), adjustment to chronic health conditions (Dear et al., 2017; Liss, Glueckauf, & Ecklund-Johnson, 2002; Shigekawa, Fix, Corbett, Roby, & Coffman, 2018) and neurorehabilitation (Johansson & Wild, 2011; Ownsworth, Arnautovska, Beadle, Shum, & Moyle, 2018; Sarfo, Ulasavets, Opare-Sem, & Ovbiagele, 2018).

Remotely delivered non-pharmacological interventions to support and improve the wellbeing of caregivers of various conditions and populations have been evaluated with promising findings (Corry, Neenan, Brabyn, Sheaf, & Smith, 2019; Glueckauf & Noël, 2011; Sherifali et al., 2018). These interventions have been delivered over the telephone, online or via mobile phone applications. Less is known with regards to how these findings translate to caregivers of adults with ABI. Due to the specific nature and distinct challenges involved in caring for someone with ABI, it is imperative that research is being carried out to explore the efficacy of remotely delivered interventions on wellbeing outcomes amongst this population.

Remote Delivery for Caregivers of Adults with ABI

Rietdijk and colleagues (2012) provide a systematic review on telehealth programs for family members of children and adults with TBI. Six papers evaluated an intervention in terms of psychological wellbeing, of which only one study had a sample of caregivers of adult TBI survivors. This particular study by Brown and colleagues (1999) evaluated a group

programme delivered over the telephone. The authors reported significant pre- to post-treatment improvements within the intervention group on measures of burden and psychological distress. It should be noted that the intervention was not completely remotely delivered as the first group session, out of a total ten, was in person. However, the study highlighted the practical benefits and the potential to improve wellbeing outcomes amongst caregivers of adults with ABI whilst utilising distance delivery.

Another summary is provided by Aldehaim and co-authors (2016) who reviewed five studies on internet-based interventions for stroke carers. Only two studies were published papers measuring validated wellbeing outcomes, out of which one trial reported significant improvement in their sample on a measure of depression. Although suggesting feasibility, it is not possible to draw any conclusions from these two reviews in terms of the efficacy of remotely delivered interventions designed to improve wellbeing amongst caregivers of adults with ABI.

The Present Review

To our knowledge, no recent reviews on this topic have been produced, and as the field of remote delivery is constantly evolving with new technology it was believed that a systematic review would be timely. The aim of the present review is thus to synthesise and evaluate the evidence for remotely delivered interventions for caregivers of adults with ABI. The literature on remote interventions tends to be divided into specific terminologies based on technologies or method of delivery such as telehealth, mHealth or web-based approaches. For the present review, however, a pragmatic stance was adopted in order to provide clinicians in the field with a summary of any type of non-pharmacological supportive or therapeutic intervention, as long as it is delivered remotely, designed to improve the wellbeing of caregivers of people with ABI. By doing so we hoped to aid the decision-making

process of clinicians who seek to offer caregivers support but who require, or wish, to do so remotely.

The two specific review questions were:

1) What is the effectiveness of interventions that are delivered remotely in terms of improving the wellbeing of informal caregivers of adults who have suffered from any type of acquired brain injury?

2) What is the quality of the evidence for interventions that are delivered remotely for this population?

Methods

Procedures

The protocol was pre-registered on the PROSPERO systematic review database (reg nr: CRD42020189235). The procedures of the present review were guided by the PRISMA systematic review guidance (Moher et al., 2009). Embase, MEDLINE, PsychInfo, Psych Articles, NeuroBITE (previously PsychBITE) and one grey literature database (opengrey.eu) were searched up until of February 2021. Searches were limited to English language; Boolean search terms were applied when possible and duplicates were removed as necessary. All databases, except NeuroBITE and the grey literature database, were searched using the OVID search engine. For the OVID search, four steps of search terms were created including variations of: type of ABI (stroke or subarachnoid* or brain haemorrhage or brain injur* or traumatic brain injur* or TBI or ABI or acquired brain injur* or encephalitis or meningitis or brain tumo* or hypox* or anox*); remote delivery (distance or remote* or home* or self-help or tele* or web* or internet or video* or biblio*); intervention (intervention or therapy or program* or support or information or training or management);

and caregiver (caregiv* or carer* or partner or significant other). Each step was first searched individually and subsequently combined with 'AND' commands to generate the final search. This search strategy was adapted to fit the additional databases. The terminology in the field is heterogeneous and the present review sought to include a variety of interventions being delivered remotely. It was therefore important to apply a broad search strategy to not miss any records. Reference lists of identified studies were hand searched for further relevant studies.

Eligibility

As recommended in the PRISMA guidance, eligibility criteria were developed from considering Population, Intervention, Control, Outcome and Study design (PICOS). Records were included if the study evaluated a remotely delivered intervention designed to directly improve the wellbeing of adults providing informal care to an adult with an ABI. All modes of delivery were of interest, and 'delivered remotely' was defined strictly as a programme being delivered without any face-to-face contact with the participant (i.e. the caregiver), and only assessments were allowed to be carried out in person as research activity. Any type of study control was included. Records had to report pre- and post-treatment outcomes using a validated instrument measuring caregiver wellbeing. Wellbeing was defined as, for example, psychological distress (e.g. depression, anxiety, stress), burden, quality of life and satisfaction with life. Secondary outcomes of interest were measures relating to the caregiver role such as caregiving mastery and caregiving satisfaction. Records were excluded if the sample included professional caregivers or care-recipients with degenerative neurological conditions (e.g. dementia). Records were also excluded if the article described a medical or pharmaceutical intervention, or if the paper had not undergone a peer-review process. Studies that were part of doctoral theses were included

as these papers undergo a process of quality control similar to that of a peer review as part of a formal assessment. As such, studies in doctoral theses were included regardless of whether they had been published in journals.

Search Process and Data Extraction

Figure 2.1 illustrates each stage of the search process. After duplicates were removed, the lead author (NR) screened the titles, and abstracts were examined if required. The full text was accessed for each record selected from the screening and matched against eligibility criteria. The second author (DS) independently reviewed 25% of the full texts selected from the initial screening, and any disagreement was resolved through discussion between NR and DS. Data were extracted from each article including study design, characteristics of the sample, details regarding the intervention, outcomes and theoretical underpinning of the intervention. Significant improvements on outcomes were extracted and effect sizes were calculated by comparison of between-group (i.e. treatment VS control) post-treatment means. Within-group improvements (i.e. pre- to post) were also extracted for both intervention and control conditions. These data could offer valuable information regarding how to best support caregivers, such as potential improvements from approaches used as control conditions.

Methodological Quality

The quality of methodology and risk of bias in the randomised and non-randomised controlled studies was assessed using the Physiotherapy Evidence Database-Partitioned (PEDroP) scale (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003; NeuroBITE, 2020). Based on the Delphi list and the original PEDro, the PEDroP is adapted to suit the neuropsychology literature, with established reliability (Maher et al., 2003; Tooth et al., 2005; Verhagen et al., 1998). The scale has been used in systematic reviews of caregiver

interventions and in the wider neurorehabilitation literature (Ownsworth & Haslam, 2016; Rietdijk et al., 2012).

The PEDroP was considered to be a suitable instrument for the present review question. An improvement from the Delphi list is that the PEDroP evaluates drop-out rates (item 8), which could be an important aspect of remote delivery. The PEDroP is suitable for both RCTs and Clinical Controlled Trials (CCT), and although no CCT was included in the evaluation this was not known prior to the searches. Moreover, due the growing use of the PEDroP in the field of neuropsychological and neurological rehabilitation research, it was thought the impact of the present review would increase in terms of generalisability by using this instrument. The NeuroBITE database consists of a large number of research trials and studies on ABI, and the majority of the records have been rated for methodological quality using the PEDroP. As such, a further benefit of using this scale was that ratings could be compared to those on the NeuroBITE database, for records that were available.

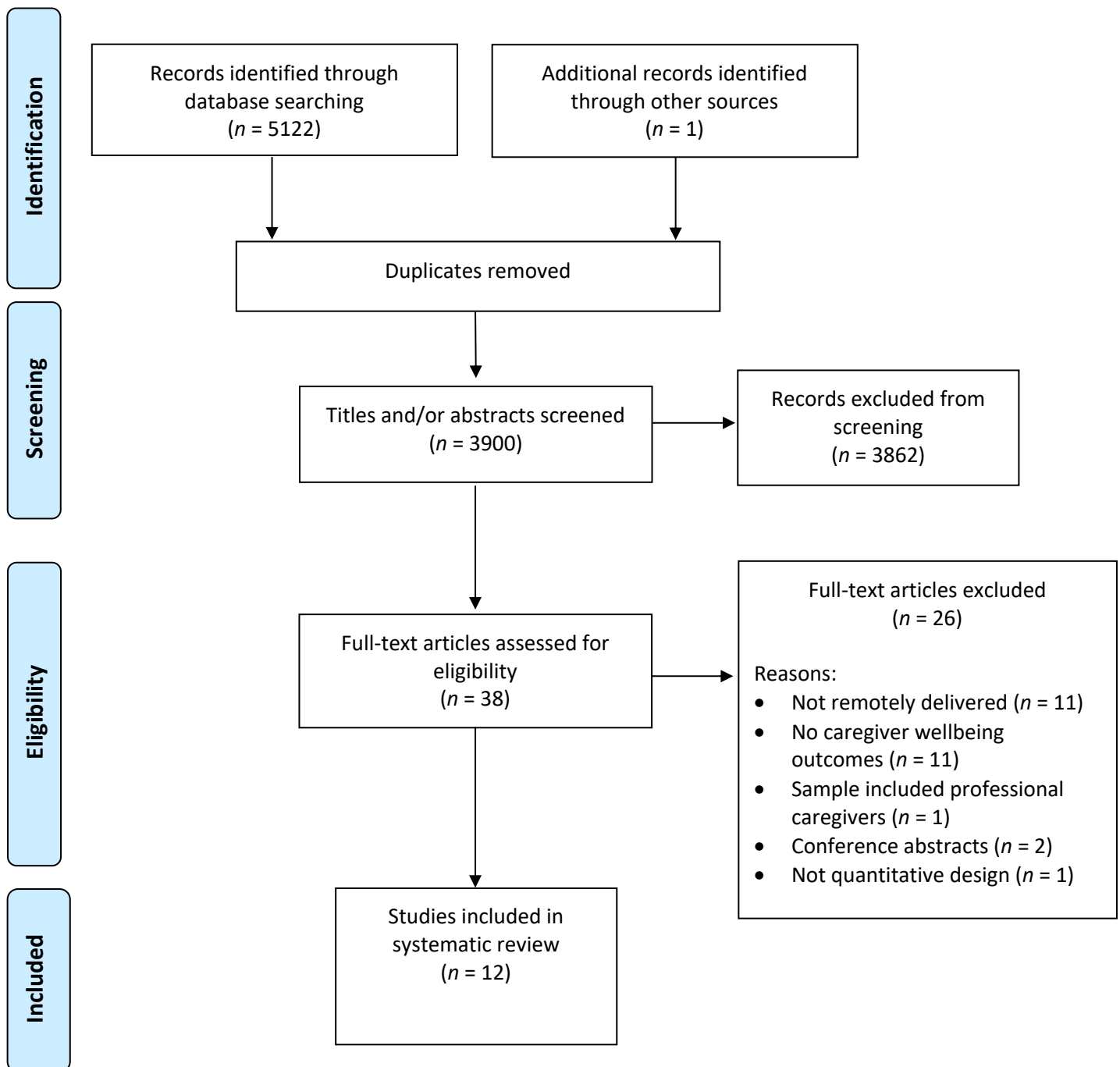
Each study received scores corresponding to specific criteria on internal validity being satisfied, with 10 being the highest total score. However, the PEDroP includes 11 criteria. This is because the first criterion relates to external validity, or generalisability, and is evaluating if the sample is explicitly depicted in the paper. Item 1 is not accounted for in the total score. The following 10 criteria (item 2-11) are all evaluating aspects of internal validity, which contribute to the total score. As such, the total score range is 0 to 10, based on criteria 2 to 11. The scores and the criteria for the PEDroP are outlined in Table 2.2. NR rated all articles on methodological quality and DS rated a randomly selected 25% of the studies independently. A substantial inter-rater agreement was observed ($k = .71, p < .001$) (Landis & Koch, 1977). Discrepancies were resolved through discussion and, when available, scoring was also confirmed by data from the NeuroBITE database.

Results

Search Process

Figure 2.1 describes the search and selection process and the results of each stage. The most common reasons for exclusion upon full-text inspection were that a study lacked caregiver wellbeing outcomes ($n = 11$) or that the intervention was not delivered remotely ($n = 11$). The search process resulted in a total number of 12 studies eligible for inclusion in this systematic review.

Figure 2.1. PRISMA Flow Diagram of the Search and Selection Process



Study Characteristics

As shown in Table 2.1, studies were published between 2001 and 2020 and originated from the United States ($n = 9$), Iran ($n = 1$), Australia ($n = 1$) and the United Kingdom ($n = 1$). The majority ($n = 10$) of the included studies employed two-armed Randomised Control Trial (RCT) designs. The remaining studies were one case series with pre-post measures (McDonald et al., 2019) and one pre-post design without any control group (Morris, 2001). In all RCT designs, the control conditions consisted of passive treatments such as Treatment as Usual (TAU) and information or attention only. In studies where TAU acted as control condition, this was described as standard medical follow-ups for the care-recipient. Information control was most often a leaflet or a website containing information about the ABI. Across all studies, sample sizes varied from very small to large ($M = 100.1$, $SD = 74.5$) ranging from 6 (McDonald et al., 2019) to 254 (Bakas et al., 2015). For RCT designs using group-based analyses, sample sizes also varied to a large degree between studies ranging from 32 (Smith et al., 2012) to 254 (Bakas et al., 2015), ($M = 115.5$, $SD = 75.8$).

Table 2.1 Summary of Study and Intervention Characteristics

Study/Country	Design/Ctrl	Sample size	ABI	Intervention target	Format and components of intervention	Mode of delivery	Delivered by	Attrition*
Bakas et al. 2015 USA	RCT Ctrl: Attention + information	N = 254	Stroke	Caregiver	Individual format Psychoeducation/Skill-building/Stress mgmt	Written material + telephone	Nurse	Int: 8.1% Tot: 8.2% ITT: Yes
Bakas et al. 2009 USA	RCT Ctrl: Attention + information	N = 50	Stroke	Caregiver	Individual format Psychoeducation/Skill-building/Stress mgmt	Written material + telephone	Nurse	Int: 19.2% Tot: 20% ITT: No
Bishop et al. 2014 USA	RCT Ctrl: TAU	N = 49	Stroke	Dyad	Individual format Psychoeducation/Problem-solving	Written material + telephone	Various	Int: not reported Tot: 38.8% ITT: Yes
Goudarzian et al. 2018 Iran	RCT Ctrl: TAU	N = 154	Stroke	Caregiver	Individual format Information/Telenursing	Telephone	Nurse	Int: 1.2% Tot: 1.2% ITT: No
Hartke and King 2003 USA	RCT Ctrl: Information	N = 124	Stroke	Caregiver	Group format Psychoeducational	Telephone	Various	Int: 36.8% Tot: 29% ITT: No
McDonald et al. 2019 Australia	Case series with pre-post Ctrl: no ctrl	N = 6	Stroke/TBI	Caregiver	Individual format Psychoeducation/Skill-building/Information	Website	-	Int: 0%
McLaughlin et al. 2013 USA	RCT Ctrl: Information	N = 201	TBI	Caregiver	Individual format Psychoeducation/Skill-building/Stress mgmt	Website	-	Int: 14% tot: 10% ITT: Yes

Milbury et al. 2020 USA	RCT Ctrl: TAU	N = 35	Brain tumour	Dyad	Individual format Therapeutic/Mindfulness	Video call	Counsellor	Int:44.4% Tot: 37.1% ITT: Yes
Morris 2001 UK	pre-post Ctrl: no ctrl	N = 34	Mixed ABI	Caregiver	Individual format Information	Written material	-	Int: 20.6% ITT: No
Pierce et al. 2009 USA	RCT Ctrl: TAU	N = 103	Stroke	Caregiver	Individual and group format Psychoeducation/Information/Social support	Website + email	Nurse + MDT	Int: 29.4% Tot: 29.1% ITT: No
Powell et al. 2016 USA	RCT Ctrl: TAU	N = 153	TBI	Caregiver	Individual format Psychoeducation/Information /Problem- solving	Written material + telephone	Social worker	Int: 23.4% Tot: 18.3% ITT: Yes
Smith et al. 2012 USA	RCT Ctrl: Information	N = 38	Stroke	Dyad	Individual and group format Psychoeducation/information/stress mgmt/Skill-building	Website + email + online chat	Nurse	Int: 36.8% Tot: 23.7% ITT: Yes

Note. 1-1 = individual-based intervention, ABI = Acquired Brain Injury, Ctrl = Control, Int = Intervention group, ITT = Intention-To-Treat, N = total sample size of study, RCT = Randomised Controlled Trial, TAU = Treatment As Usual, TBI = Traumatic Brain Injury; Tot = total attrition rate

* = Attrition rates were calculated from participants dropping out between being allocated and post-treatment assessment

Appraisal of Methodological Quality

The evaluation of methodological quality of RCTs ($n = 10$) is detailed in Table 2.2. In summary, the methodological quality was generally acceptable, and varied somewhat between studies. The PEDroP scale has a score range between 0 and 10, with 10 representing excellent methodological standard. The assessment of the reviewed sample yielded PEDroP scores ($M = 5.6$, $SD = 1.3$) ranging from 4 (Hartke & King, 2003; Milbury et al., 2020; Pierce, Steiner, Khuder, Govoni, & Horn, 2009) to 8 (Bakas et al., 2015).

Several themes were identified from the appraisal of methodological quality. No study received scores for blinding of subjects or therapists. Although a common issue in psychosocial intervention research, there is a significant risk of performance bias from participants, in addition to the risk of preferential treatment by clinicians delivering the intervention under investigation. Attrition rates were high in most studies. As visible in Table 2.2, and in the right column in Table 2.1, only three studies had a total sample attrition rate below 15% (Bakas et al., 2015; Goudarzian, Fallahi-Khoshknab, Dalvandi, Delbari, & Biglarian, 2018; McLaughlin, Glang, Beaver, Gau, & Keen, 2013). Attrition rates for intervention groups ($M = 23.7\%$) ranged from 1.2% (Goudarzian et al., 2018) to 44.4% (Milbury et al., 2020). Only six out of ten controlled studies employed intention-to-treat analysis. In fact, three studies had drop-out rates above 15% as well as lacking intention-to-treat analysis (Bakas et al., 2009; Hartke & King, 2003; Pierce et al., 2009).

In addition to the PEDroP ratings, another methodological shortcoming was a lack of power. Only two studies provided a-priori power calculations that was adhered to in order to recruit a large enough sample for sufficient power (Bakas et al., 2015; Pierce et al., 2009).

There were also methodological strengths noted. All appraised studies presented between-group analysis with inferential statistics. Similarly, all but one paper provided both

point estimates and variability for their results. All studies ensured participants were allocated using randomisation, and eligibility criteria was clearly outlined in all papers.

Table 2.2 Ratings of Methodological Quality of Controlled Trials

	1. Eligibility criteria was specified	2. Allocation was random	3. Allocation was concealed	4. Intervention groups were similar at baseline	5. There was blinding of all subjects	6. There was blinding of all therapists	7. There was blinding of all assessors ^a	8. Outcomes were obtained from > 85% of the sample ^{b, d}	9. Subjects received condition/ intention- to-treat analysis ^c	10. Between- group statistical comparisons ^d	11. Point measures and variability ^d	Total (Item 2-11)
Bakas et al. 2015	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8/10
Bakas et al. 2009	N	Y	Y	Y	N	N	Y	N	N	Y	Y	6/10
Bishop et al. 2014	Y	Y	N	Y	N	N	Y	N	Y	Y	Y	6/10
Goudarzian et al. 2018	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5/10
Hartke and King 2003	Y	Y	Y	N	N	N	N	N	N	Y	Y	4/10
McLaughlin et al. 2013	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7/10
Milbury et al. 2020	Y	Y	Y	N	N	N	N	N	Y	Y	N	4/10
Pierce et al. 2009	Y	Y	N	Y	N	N	N	N	N	Y	Y	4/10
Powell et al. 2016	Y	Y	Y	N	N	N	Y	N	Y	Y	Y	6/10
Smith et al. 2012	Y	Y	Y	N	N	N	Y	N	Y	Y	Y	6/10

Note. a = who measured at least one key outcome; b = of participants allocated to groups; c = for subjects of which outcome measures were available, and for at least one key outcome; d = for at least one key outcome

Participant Characteristics

Combined, the studies selected for this review involved 1195 caregivers of which the majority (72%) were female (range = 57% - 100%). The mean caregiver age in the reviewed studies ranged from 49 (Goudarzian et al., 2018) to 69 (Hartke & King, 2003). All but three samples had a majority of spouses or partners. For the three additional studies, one had a sample of which the majority were parents (Morris, 2001), and in two studies the relationship was more broadly defined as being a family member (Goudarzian et al., 2018; McLaughlin et al., 2013). In studies providing data on care-recipients characteristics, these involved a total of 847 individuals of which the majority were male (62%), but samples ranged from 34.7% to 100% in terms of male gender of the care-recipients (Bakas et al., 2009, 2015; Bishop et al., 2014; McDonald et al., 2019; McLaughlin et al., 2013; Milbury et al., 2020; Pierce et al., 2009; Powell et al., 2016; Smith et al., 2012).

Mean sample age of care-recipients ranged from 42 (Powell et al., 2016) to 70 (Bishop et al., 2014). As can be seen in Table 2.1, most ($n = 7$) studies recruited caregivers of stroke survivors whilst two studies involved only caregivers of people with TBI (McLaughlin et al., 2013; Powell et al., 2016). Two studies included a mix of ABIs (McDonald et al., 2019; Morris, 2001) and one additional study investigated an intervention for caregivers of people with brain tumour (Milbury et al., 2020).

Interventions

All but three interventions were delivered in an individual format to either the caregiver (Bakas et al., 2015, 2009; Goudarzian et al., 2018; McDonald et al., 2019; McLaughlin et al., 2013; Morris, 2001; Powell et al., 2016) or to a dyad of caregiver and care-recipient (Bishop et al., 2014; Milbury et al., 2020). The exemptions were one study which evaluated a group-based intervention (Hartke & King, 2003), and two studies describing

interventions consisting of both group- and individual-based formats (Pierce et al., 2009; Smith et al., 2012). Six interventions were delivered over the telephone (Bakas et al., 2015, 2009; Bishop et al., 2014; Goudarzian et al., 2018; Hartke & King, 2003; Powell et al., 2016), four interventions through a website (McDonald et al., 2019; McLaughlin et al., 2013; Pierce et al., 2009; Smith et al., 2012), one intervention via video call (Milbury et al., 2020) and one utilised only written material (Morris, 2001).

All but one of the twelve interventions were delivered within the first year of the care-recipient being discharged from hospital, whilst the intervention in Hartke and King (2003) was offered to caregivers during inpatient rehabilitation. Interventions were most often delivered by a nurse (Bakas et al., 2009, 2015; Goudarzian et al., 2018; Pierce et al., 2009; Smith et al., 2012). One intervention was delivered by a counsellor (Milbury et al., 2020), one by a social worker (Powell et al., 2016), and two interventions were being delivered by professionals from various disciplines (Bishop et al., 2014; Hartke & King, 2003). Seven interventions were developed based on specific theoretical frameworks (Bakas et al., 2009, 2015; Bishop et al., 2014; Hartke & King, 2003; Milbury et al., 2020; Pierce et al., 2009; Powell et al., 2016; Smith et al., 2012), where the most common model ($n = 4$) was the stress-process model or variations of this (Bakas et al., 2009, 2015; Hartke & King, 2003; Smith et al., 2012).

The majority ($n = 9$) of interventions had a psychoeducational focus, either on its own or in combination with other modules (Bakas et al., 2009, 2015; Bishop et al., 2014; Hartke & King, 2003; McDonald et al., 2019; McLaughlin et al., 2013; Pierce et al., 2009; Powell et al., 2016; Smith et al., 2012). Psychoeducation involved the provision of normalising information about emotional difficulties associated with being a caregiver and potential ways to cope with these. Four interventions involved stress-management modules

(Bakas et al., 2009, 2015; McLaughlin et al., 2013; Smith et al., 2012). McLaughlin et al. (2013) presented a web-based multi-component intervention where stress-management was defined as specific strategies such as healthy living and relaxation exercises. Two studies (Bishop et al., 2014; Powell et al., 2016) described interventions that used a problem-solving approach based on problem-solving therapy (Nezu, Nezu, & D’Zurilla, 2013). The aim with problem-solving was to improve the caregiver’s self-effectiveness and emotional management. Only one intervention utilised a psychotherapeutic model to improve psychological wellbeing amongst caregivers (Milbury et al., 2020). Milbury and colleagues (2020) described a mindfulness-based therapeutic intervention via online video delivery. Many interventions involved components targeting more practical aspects of caregiving, such as skill-building (Bakas et al., 2009, 2015; McDonald et al., 2019; McLaughlin et al., 2013; Smith et al., 2012), information provision about the particular ABI (Goudarzian et al., 2018; McDonald et al., 2019; Morris, 2001) and didactic nursing instructions (Goudarzian et al., 2018).

Table 2.3 Summary of Efficacy on Caregiver Wellbeing Outcomes

Study and outcomes (measure)	Between-group differences (Effect size)*	Within-group changes
Bakas et al. 2015		
Depression (PHQ-9)	ns	Intervention improvements from pre- to post-treatment and FU
Life changes (BCOS)	ns	Intervention improvements from pre- to post-treatment and FU
Bakas et al. 2009		
Depression (PHQ-9)	ns	-
General health (SF-36GH)	ns	-
Threat appraisal (ACS)	In favour of intervention at post ($d = -0.85$) and FU ($d = -0.77$)	-
Life changes (BCOS)	ns	-
Difficulty with tasks (OCBS)	ns	-
Optimism (LOT-R)	In favour of intervention at post ($d = 0.87$) and FU ($d = 0.89$)	-
Bishop et al. 2014		
Depression (GDS)	ns	-
Family functioning (FAD)	In favour of intervention at post-treatment ($d = 0.81$)	-
Criticism (PCS)	In favour of intervention at post-treatment ($d = -0.95$)	-
Goudarzian et al. 2018		
Depression (BDI)	ns	Intervention & ctrl group improvements from pre- to post-treatment
Anxiety (BAI)	In favour of intervention at post-treatment ($d = -0.57$)	Intervention improvements from pre- to post-treatment
Hartke and King 2003		
Depression (CES-D)	ns	ns
Burden (BI)	In favour of intervention at FU ($d = -0.36$)	ns
Stress (PPI)	ns	Intervention improvements from pre- to post-treatment and FU
Loneliness (UCLA)	ns	ns
Competence (CCS)	In favour of intervention at FU ($d = 0.28$)	ns
McDonald et al. 2019		
Depression (DASS-21)	n/a	1/6 participants reported reliable improvement
Anxiety (DASS-21)	n/a	1/6 participants reported reliable improvement
Stress (DASS-21)	n/a	2/6 participants reported reliable improvement
Strain (CSI)	n/a	0/6 participants reported reliable improvement
McLaughlin et al. 2013		
Satisfaction with life (SWLS)	ns	-
Milbury et al. 2020		
Depression (CES-D)	ns	-
Mindfulness (MAAS)	ns	-

	Compassion (SCS)	ns	-
	Intimacy (PAIRI)	ns	-
Morris 2001			
	Anxiety (HADS)	n/a	ns
	Distress (GHQ)	n/a	ns
Pierce et al. 2009			
	Depression (CES-D)	ns	ns
	Satisfaction with life (SWLS)	ns	ns
Powell et al. 2016			
	Distress (BSI-18)	In favour of intervention at post-treatment ($d = -0.41$)	-
	Quality of life (BCOS)	ns	-
	Mastery (MCAS)	ns	-
Smith et al. 2012			
	Depression (CES-D)	In favour of intervention at post ($d = -0.79$) and FU ($d = -0.53$)	-
	Self-esteem (SES)	ns	-
	Mastery (MS)	ns	-
	Social Support (MOS)	ns	-

Note. ACS = Appraisal of Caregiving Threat Subscale, BAI = Beck Anxiety Inventory, BCOS = Bakas Caregiving Outcomes Scale, BDI = Beck Depression Inventory, BI = The Burden Interview, BSI-18 = Brief Symptom Inventory, CCS = The Caregiver Competence Scale, CES-D = The Center for Epidemiologic Studies– Depression Scale, CSI = The Carer Strain Index, DASS-21 = Depression Anxiety and Stress Scale, FAD = Family Assessment Device, GDS = The 13-item Geriatric Depression Scale, GHQ = General Health Questionnaire, HADS = Hospital Anxiety and Depression Scale, LOT-R = The Revised Life Orientation Test, MAAS = Mindful Attention Awareness Scale, MCAS = Modified Caregiver Appraisal Scale, MOS = MOS social support survey, MS = Mastery Scale, OCBS = Oberst Caregiving Burden Scale Difficulty Subscale, PAIRI = Personal Assessment of Intimacy in Relationships Inventory, PCS = Perceived Criticism Scale, PHQ – 9 = The Patient Health Questionnaire, PPI = The Pressing Problem Index, SCS = Self-Compassion Scale, SES = Self-Esteem Scale, SF-36GH = The SF-36 Health Survey General Health Subscale, SWLS = The Satisfaction with Life Scale, UCLA = The UCLA Loneliness Scale

* = Negative sign on effect size indicates that reduced score equals improvement on measure, FU = Follow-up, n/a = Not applicable due to study design

Outcomes

Table 2.3 shows the outcomes of each study. Across the reviewed studies ($N = 12$), a total of 29 different psychometric instruments were used to measure the efficacy of interventions on a total of 23 outcomes directly or indirectly relating to caregiver wellbeing. Further details regarding outcome measures, results and effect sizes are provided in Table 2.3. Effect sizes are Cohen's d , where small, medium and large corresponds to effect sizes over 0.20, 0.50 and 0.80, respectively (Cohen, 1988).

Psychological Distress

Depression was explored in the majority ($n = 9$) of the reviewed studies (Bakas et al., 2009, 2015; Bishop et al., 2014; Goudarzian et al., 2018; Hartke & King, 2003; McDonald et al., 2019; Milbury et al., 2020; Pierce et al., 2009; Smith et al., 2012). Three studies reported significant improvements on measures of depression (Bakas et al., 2015; Goudarzian et al., 2018; Smith et al., 2012). Goudarzian and colleagues compared a telephone-based nursing programme to TAU in a sample of stroke caregivers ($N = 154$). The study found significant within-group changes (i.e. pre to post improvements) in both conditions on depression scores, but there was no significant difference between the intervention and control at post-treatment. Similarly, Bakas and co-authors (2015) did not find a significant between-group difference when a telephone-based skill-building intervention was compared to attention-only control in a large sample ($N = 254$) of stroke caregivers. They did find a significant within-group improvement in the intervention group ($n = 123$) from pre- to post-treatment, which was maintained one year later. Moreover, when analysing only a subgroup of participants with higher symptoms of depression at baseline (i.e. PHQ-9 ≥ 5) the authors found a significant difference in depression scores between the treatment condition ($n = 58$) and control ($n = 66$) at post-treatment. Smith and colleagues (2012) evaluated an

intervention delivered online to dyads utilising a mixture of group and individual formats and targeting both emotional and practical aspects of caregiving. The sample size was relatively small ($N = 32$) and the treatment effect had a medium, approaching large, effect size ($d = -0.79$) when compared to control at post-treatment, which was maintained at follow-up one month later.

Anxiety was investigated in three studies with mixed findings. Goudarzian and colleagues (2018) found significant reductions on the Beck's Anxiety Inventory within the treatment group ($d = -0.77$), and a significant difference between the groups at post-treatment in favour of the intervention ($d = -0.57$). In contrast, Morris (2001) did not find a significant pre- to post- improvement on anxiety from providing caregivers with written information about ABI and caregiving. In a case series, McDonald and colleagues (2019) only found that one out of six participants reported a reliable improvement on a measure of anxiety. The intervention supported caregivers of adults with TBI and challenging behaviour by providing skill-building and psychoeducation through an online platform.

Two studies investigated distress as a general outcome (Morris, 2001; Powell et al., 2016). Powell and colleagues found a significant reduction in distress for caregivers who took part in a telephone-delivered intervention ($n = 77$), when compared to participants who received TAU as control ($n = 76$). Their intervention combined information about ABI, psychoeducation and problem-solving strategies. In contrast, Morris (2001) did not find a significant decrease in overall distress ratings.

Quality of Life (QoL)

Three studies explored caregiver-specific QoL, which was also conceptualised as *life changes* (Bakas et al., 2015, 2009; Powell et al., 2016). All three studies measured QoL using the 15-item Bakas Caregiving Outcomes Scale (BCOS) (Bakas, Champion, Perkins, Farran, &

Williams, 2006). A significant within-group improvement was found in Bakas et al. (2015) at post-treatment and this was maintained at follow-up one year later. The additional two studies did not observe any significant improvements on QoL in their samples. Two studies investigated the efficacy of remotely delivered interventions on increasing satisfaction of life without finding any significant benefits in this area (McLaughlin et al., 2013; Pierce et al., 2009).

Burden and Stress

Only one study investigated burden as an outcome (Hartke & King, 2003). The study evaluated a telephone-based group-based intervention for spouses of stroke survivors in an acute rehabilitation setting. Participants attended eight weekly teleconference sessions consisting of primarily psychoeducation. The author's found a significant treatment effect with a small effect size ($d = -0.36$) when compared to controls. Hartke and King (2003) found no significant between-group differences to the control condition on stress, but the intervention group reported significant within-group reductions in stress from pre- to post-treatment. MacDonald and colleagues (2019) reported that two out of six participants in their case series had a reliable reduction in levels of stress.

Additional Wellbeing Outcomes

Several additional outcomes were investigated which are directly related to wellbeing. Bishop and colleagues (2014) reported significantly larger improvements in family functioning and perceived criticism of the caregiver in their intervention group compared to control at post-treatment. The intervention consisted of structured problem-solving and psychoeducation and was delivered to dyads via the telephone. Bakas et al. (2009) found significantly greater changes on measures of optimism and threat appraisal in favour of the intervention at both post-treatment and follow-up. The intervention was developed from

stress-coping theory and incorporated stress management strategies based on Cognitive Behaviour Therapy (Beck, 1976; Lazarus & Folkman, 1984). No significant benefits were reported, in the reviewed studies, for loneliness (Hartke & King, 2003), self-esteem (Smith et al., 2012) mindfulness, compassion or intimacy (Milbury et al., 2020).

Secondary outcomes

In addition to wellbeing outcomes, several studies investigated concepts relating to the caregiver situation, and which could have an indirect impact on an individual's wellbeing. In their RCT, Hartke and King (2003) found that caregivers who received psychoeducation via a teleconference intervention reported a greater sense of competence, compared to controls. The effect size was small, approaching medium ($d = 0.28$). Mastery and social support was investigated in two papers but no significant changes were reported in these studies (Powell et al., 2016; Smith et al., 2012).

Discussion

The aims of this systematic review were to investigate the efficacy of remotely delivered interventions on wellbeing outcomes amongst caregivers of adults with ABI, and to evaluate the methodological quality of the evidence. Twelve studies were identified from the search process. These studies evaluated interventions delivered over the telephone, online, via videoconferencing and written material. Most interventions were offered within the first year following the ABI and had a focus on psychoeducation, with only one study evaluating a therapeutic intervention. A wide range of wellbeing outcomes were investigated across the twelve studies.

The Efficacy of Remotely Delivered Interventions for Caregivers of Adults with ABI

In terms of the first aim, preliminary evidence for the efficacy of remote delivery was found in wellbeing areas such as psychological distress (Bakas et al., 2015; Goudarzian et al., 2018; Powell et al., 2016; Smith et al., 2012), quality of life (Bakas et al., 2015) and burden (Hartke & King, 2003). Improvements in some additional outcomes such as family functioning (Bishop et al., 2014), optimism and threat appraisal (Bakas et al., 2009) were also reported in the reviewed studies. These findings are consistent with earlier reviews on telehealth and technology-based approaches for caregivers of people with TBI and stroke (Aldehaim et al., 2016; Rietdijk et al., 2012). Compared to previous reviews, this is the first systematic review synthesising studies evaluating any type of remotely delivered intervention for caregivers of any type of ABI.

Although the results indicate that remotely delivered interventions have the potential to benefit caregivers' wellbeing, there were several reviewed studies that did not provide evidence for this. A lack of efficacy was particularly obvious for depression. This finding is in line with previous reviews on remotely delivered interventions for caregivers of people with conditions other than ABI (Corry et al., 2019). The prevalence of depression amongst caregivers over-all is estimated to be significantly higher than in the general population (Pinquart & Sörensen, 2003). Traditionally delivered psychological interventions, such as psychotherapy and counselling, have been found superior to skill-based or psychoeducational approaches in terms of improving psychological distress amongst caregivers of various conditions, but evaluations on ABI carers are lacking (Forster et al., 2012; Panzeri et al., 2019; Sörensen et al., 2002). In the present review only one of twelve studies employed a therapeutic approach.

This lack of research into potential psychological interventions for ABI caregivers is another barrier for access to evidence-based support for this group. Existing evidence from research on dementia caregivers suggests that both traditional Cognitive Behavioural Therapy (CBT) and, more recently, Acceptance and Commitment Therapy (ACT) have shown promise when applied to caregivers (Losada et al., 2015; Pachana, Laidlaw, Márquez-González, Losada, & Romero-Moreno, 2015). Internet-based ACT has good engagement rates, and can be effective for depression, anxiety and quality of life in cross-diagnostic samples, although with small effect sizes (Thompson, Destree, Albertella, & Fontenelle, 2020). CBT has also been found to be efficacious when delivered remotely to dementia caregivers (Scott et al., 2016).

Methodological Quality

In terms of the second question this review set out to answer, the overall methodological quality was adequate. Certain methodological weaknesses and biases were identified across the studies, and the findings must be interpreted with caution and in the light of these themes. The majority of controlled studies compared an intervention to a passive condition. As such, findings from these comparisons simply tell us if a remote intervention is more effective than a low-level control condition. There would be further benefits in evaluating a remotely delivered intervention on its efficacy when compared to face-to-face delivery, which has been done in other areas (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018).

Attrition rates in most of the reviewed studies ($M = 23.7\%$) were high enough to lose points on the PEDroP appraisal tool. However, average attrition reported for in-person cognitive therapy has been estimated to similar rates as the studies in the present review (Fernandez, Salem, Swift, & Ramtahal, 2015).

Sample sizes varied greatly across studies and many trials lacked sufficient power for between-group analyses. There was a tendency to attribute small sample sizes to the fact that the study intended to pilot or assess feasibility of an intervention. Small sample sizes are common occurrence in pilot trials and not an issue per se. However, when outcome data is presented from between-group analyses small sample sizes increase the risk of not finding an effect when there is one (i.e. Type II error). It is clear from Table 2.3 that the reviewed studies produced a large amount of non-significant findings, and low power to detect effects could be one possible reason for this. Studies with larger sample sizes also reduce the risk of sampling bias, which improve effect size estimates and reducing the potential for type I errors (Lakens, 2013).

Several studies reported low baseline depression scores (e.g. Bakas et al., 2015; Milbury et al., 2020; Pierce et al., 2009). Similarly, Bakas and colleagues (2015) only found a significant difference between intervention and control when they analysed a sub-group of participants with higher depression scores at baseline. In fact, the only study in the present review that reported a significant between-group difference on depression used a cut-off score of 5 on the PHQ-9 as an inclusion criterion for participation (Smith et al., 2012). Taken together, it is possible that low baseline scores could have contributed to the lack of significant reductions on depression measures that was seen in the reviewed sample of studies.

Limitations of the Present Review

The search process was carried out manually by the lead author and although great care was taken to devise relevant and specific search terms there is still a risk that existing records were missed and therefore not represented in this review. For example, the term

head injury, and the American spelling of *hemorrhage* were not included in the search strategy, which introduces the risk that relevant records could have been missed.

The majority of the selection process and the rating of methodological quality was carried out by the lead author which introduces a degree of subjectivity. It is believed that by having the second author to select and rate a number of the reviewed papers this subjectivity was minimised. It was decided from the outset that only outcomes relating to the caregiver would be included. Caregivers and care-recipients often co-exist in dyads, and one could argue that a change on a care-recipient outcome would impact on the wellbeing of the caregiver. This link is not represented here and might limit the results of this review.

Effect sizes were transformed to Cohen's d for all effects in order to ease interpretation and data accessible in the records were used to calculate these whilst authors were contacted for missing data. Insufficient information (i.e. correlation data between pre- and post-treatment) to estimate effect sizes for the three articles reporting significant within-group changes led to the decision to omit this data rather than risk presenting inaccurate effects (Lakens, 2013). Attempts were made to retrieve this information from other sources. Consequently, effect sizes for within-group effects are not presented.

The present review sought to synthesise the research on remote interventions for caregivers of any type of ABI. From the results, it is clear that the majority of records found reported outcomes on samples consisting of caregivers of stroke survivors. In hindsight, narrowing the review aim to only evaluate remote stroke caregiver interventions would have resulted in a more homogeneous sample of studies. However, it should be noted that there was a large degree of heterogeneity between studies on stroke carers in terms of interventions and outcome measures.

Clinical Implications

It is premature to make blanket statements regarding the efficacy of remotely delivered interventions on wellbeing outcomes amongst of ABI caregivers. However, two large sample and high quality studies in the present review can be interpreted with some confidence. The findings from Bakas et al. (2015) and McLaughlin et al. (2013) suggest that an intervention consisting of psychoeducation, stress management and skill-building can be effective to reduce depression in stroke carers, but not to improve satisfaction of life amongst TBI carers. In both studies, the intervention was no more effective than control. Control conditions in these studies consisted of the provision of information only, or in combination with weekly phone calls (attention control).

These results indicate that low intensity approaches, such as the provision of information and limited support, could potentially be enough to support some caregivers, whilst being less resource demanding on services. In practice, this type of low-intensity intervention could be offered via services' websites, or over the telephone if a member of a multidisciplinary team has allocated time to respond to queries directly. Another benefit with low intensity approaches would be the potential to offer these in high volumes, and with preventative aims, which is in line with developments in general mental health services (Bennett-Levy et al., 2010).

Considerations for Future Research

As mentioned above, the majority of studies identified evaluated an intervention for caregivers of stroke survivors. This finding is in line with research on traditional face-to-face interventions for caregivers of people with brain injury, which is somewhat skewed towards stroke and TBI carers. One probable reason for this skew is the higher prevalence of stroke and TBI compared to other brain injuries such as infectious conditions, tumours or hypoxic

injury. However, there is a remaining gap in our knowledge with regards to the efficacy of support interventions for caregivers of people with additional brain injuries that come under the ABI terminology (Boele et al., 2013; Piil, Juhler, Jakobsen, & Jarden, 2016).

Across the twelve studies, eleven different interventions were evaluated on a large number of outcomes. This heterogeneity makes it difficult to make direct comparisons between studies in terms of efficacy, and to make broader comments regarding effectiveness with any degree of confidence. This is a well-known issue in the literature on traditional caregiver interventions and it highlights the need for replication of positive results to confirm the efficacy of an intervention over time and across samples (Boschen et al., 2007; Kreitzer et al., 2018). For example, Bakas et al (2015) found contrasting findings in the second evaluation of a telephone-based programme using a design with larger sample size and more rigorous methodology.

In summary, the present review can offer the following recommendations and suggested directions for future research into remotely delivered interventions for caregivers of adults with ABI:

- 1) Future studies should compare a remotely delivered intervention to the same package delivered face-to-face.
- 2) Larger sample sizes and a-priori power calculations are needed in order to reduce the risk of type 2 errors (i.e. false negatives) and sample biases.
- 3) In order to facilitate future review work, it is recommended that studies provide sufficient data in the results section or in supplementary documentation to make necessary calculations of both between- and within-group effect sizes. This would include data for means and standard deviations for baseline and post-intervention, and correlation data between pre- and post-intervention (i.e. test-retest reliability of the measure).

4) Develop a consistent approach to outcomes of future evaluations. Depression, anxiety, quality of life and satisfaction with life are potential candidates that can be measured using validated and well-established psychometric instruments translated into multiple languages.

5) Uphold a consistent approach to developing intervention frameworks using explicit theoretical models and ensure consistency in practical aspects such as treatment target, modes of delivery, number/type of modules, time of delivery and settings.

6) Evaluate remotely delivered psychological interventions, therapeutic models or counselling approaches in order to target psychological distress amongst ABI caregivers. Ideally, this type of intervention would be compared to a low-intensity approach and;

7) Evaluate differences between less distressed versus more distressed caregivers on the same intervention.

8) Include caregivers of people with ABIs other than stroke and TBI to assess if different groups have distinctive support needs and different responses to interventions. Alternatively, evaluate a generic model of caregiver intervention across various conditions.

Conclusion

Findings from this review suggest that remote delivery has potential to improve access to services for caregivers of people with ABI. Albeit limited, there is promising evidence that interventions may be beneficial in terms of anxiety, burden, and in some studies depression, whilst being delivered remotely. Low-intensity control conditions were in some studies found to be just as effective as structured programmes, and future exploration into this area is encouraged. These findings should be interpreted with caution due to a limited number of studies, small sample sizes and heterogeneity in terms of interventions and outcomes, which underscores the need for further research.

Thesis Conclusion

Chapter one presented a study exploring the role of psychological flexibility, compared to established constructs, on depression, anxiety and satisfaction with life amongst a sample of 144 caregivers of adults with an ABI. Psychological flexibility accounted for most variance in depression and anxiety, whilst negative appraisals were the strongest predictor of satisfaction of life. Psychological flexibility was found to have a buffering role on depression, moderating the effect of appraisal. These findings are adding to previous conceptualisations of caregiver distress and wellbeing and suggest that psychological flexibility has a central role worth exploring further. From these results, it was recommended that studies with larger samples are now to be conducted, and that longitudinal or treatment trials are considered in order to replicate these findings and to examine causality.

The study in chapter one illustrated the important role of psychological factors in our understanding of distress and wellbeing amongst ABI carers. In contrast to contextual factors, such as the level of functional disability of the care-recipient, these psychological factors are modifiable via intervention. Although there is now a growing evidence-base suggesting a key role of psychological factors, and the potential for interventions, there is a gap between theory and practice. Likewise, caregivers face various barriers in order to access supportive interventions. Remotely delivered interventions have the potential to overcome these barriers and improve implementation of interventions to support the wellbeing of caregivers of people with ABI.

The second chapter of this thesis investigated the state of the research on remotely delivered interventions designed to improve the wellbeing of ABI carers. Twelve studies

were identified, which evaluated a wide range of supportive interventions for ABI carers on various wellbeing outcomes. Preliminary evidence of the benefit of remotely delivered interventions were found for some outcomes, such as anxiety, burden and in a few studies also depression. However, due to few controlled trials, small sample sizes, and a heterogeneity across studies and outcomes it was concluded that these early findings must be interpreted with caution. It was also evident that psychological interventions were lacking, and in some trials low-intensity input used as control condition had similar effect as a structured intervention.

In conclusion, this thesis has demonstrated that constructs such as psychological flexibility and cognitive appraisals are important processes to better understand distress and wellbeing amongst caregivers of people with ABI. As such, these findings are well suited to contribute to the development of future interventions. Remote delivery is an alternative approach to offer interventions targeting these processes. Despite some encouraging findings, there is only a limited amount of research on interventions being delivered remotely for ABI carers. In particular, treatment trials investigating psychological approaches are needed, and could further clarify causal relationships between predictors and outcomes. From the findings here, suitable candidates would be Acceptance and Commitment Therapy (ACT) or traditional cognitive therapy.

Caregivers are key collaborators to neurorehabilitation services and play a central role in the lives of people with ABI. It is hoped that the conclusions of this thesis have added to our knowledge in terms of how to support this population.

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Appendices

Appendices for Chapter One

Appendix 1A: Study Material

Figure 1A.1 Study recruitment poster

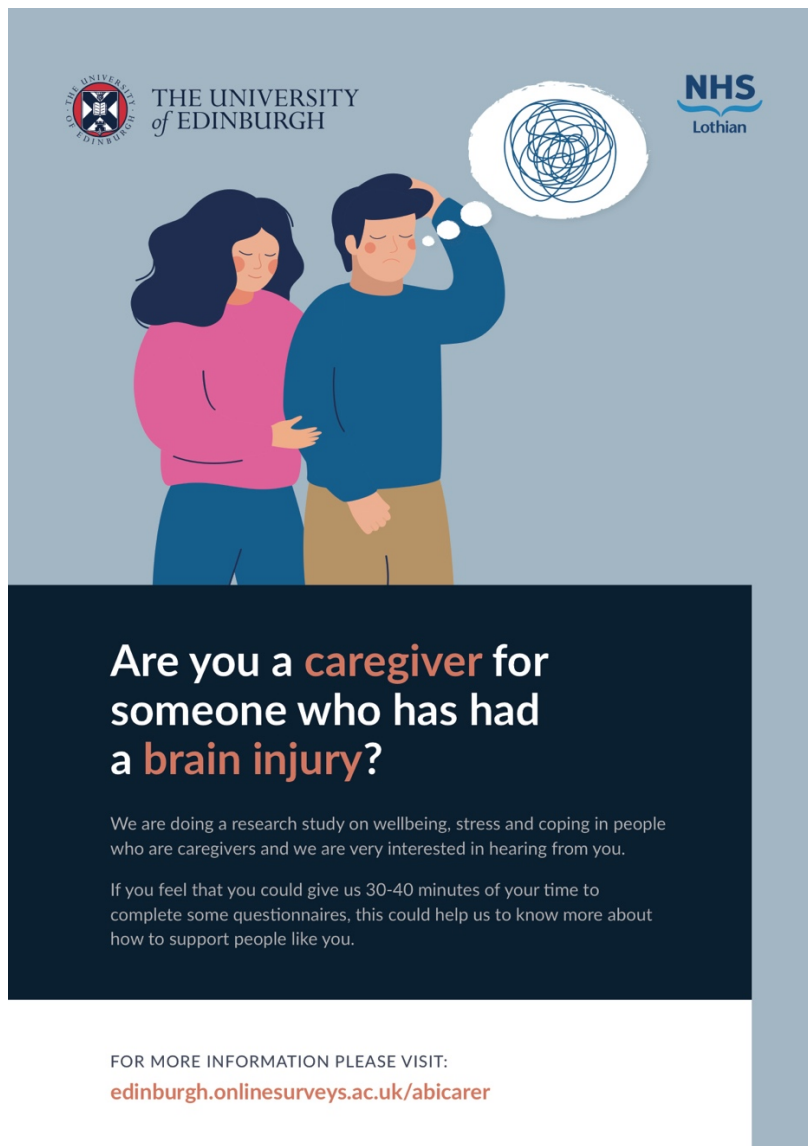


Figure 1A.2 Part of information sheet

ABI Carer Study

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Participant Information

Welcome to the ABI Carer Study. You are invited to take part in this research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

Acquired Brain Injuries (ABI) can have a significant impact on the individual and people in their lives. Family members and friends often take on the role of caregiver in various ways. Caregivers play a key role in the rehabilitation and daily life of people who have suffered from an acquired brain injury. Studies have shown that being a caregiver can be stressful, and in some cases, can be associated with anxiety and depression. The purpose of this study is to investigate what factors influence wellbeing and distress in people who provide care for someone with an acquired brain injury. Knowing more about these factors could improve interventions to support caregivers in the future.

Why have I been invited to take part?

You have been invited to take part in this study because you are a caregiver of someone with an acquired brain injury. Acquired brain injuries are injuries to the brain that occurred after birth. Here are some examples of common acquired brain injuries, although this list is not conclusive:

Figure 1A.3 Part of consent form

Consent form

Before you can start the questionnaires, we need to know that you agree to take part in this study. Please read the statements below and tick all boxes to confirm you consent to taking part.

1. I confirm that I have read and understand the information page for this study presented on the previous webpage, and that I fulfill the criteria for participation. Please tick all items below to continue. * *Required*

Please select at least 6 answer(s).

- ☐ I am an unpaid caregiver over the age of 16
- ☐ I can understand written English
- ☐ The person I care for is over the age of 16
- ☐ The person I care for has suffered from an acquired brain injury of any kind that occurred after the age of 16.
- ☐ The person I care for has been discharged from hospital (in relation to the ABI) for more than 3 months
- ☐ The person I care for does not have a diagnosis of a degenerative or progressive neurological condition or disease (e.g. any type of dementia, multiple sclerosis, Parkinson's disease or motor neuron disease).

2. I understand that my participation is voluntary and that I am free to withdraw at any time prior to submitting my responses, without giving any reason and without my medical care and/or legal rights being affected. * *Required*

☐ Please tick to confirm

3. I understand that relevant sections of my anonymous data collected during the study may be looked at by individuals from the Sponsors (University of Edinburgh and NHS Lothian) from

Appendix 1B: Ethical Approval

Figure 1B.1 Page one of letter of ethical approval from REC



**Office for Research Ethics Committees
Northern Ireland (ORECNI)**

Customer Care & Performance Directorate

Unit 4, Lissue Industrial Estate West
Rathdown Walk
Moir Road
Lisburn
BT28 2RF
Tel: 028 9536 1400
www.hscbusiness.hscni.net/orecni

Health and Social Care Research Ethics Committee B (HSC REC B)

20 November 2019

Mr Nils Rickardsson
Clinical Neuropsychology Dept.
Astley Ainslie Hospital
133 Grange Loan
Edinburgh
EH9 2HL

Dear Mr Rickardsson

Study title:	Caring for Someone with an Acquired Brain Injury: the Role of Psychological Flexibility
REC reference:	19/NI/0215
Protocol number:	CAHSS1910/03
IRAS project ID:	269409

The Proportionate Review Sub-committee of the HSC REC B reviewed the above application on 18 November 2019. The Sub-committee commended the research team for a very well written research proposal.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Providing Support to Health and Social Care



Figure 1B.2 Final page of letter of ethical approval from REC**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

With the Committee's best wishes for the success of this project.

19/NI/0215

Please quote this number on all correspondence

Yours sincerely



pp. Melissa Stewart
Dr Anne Moorhead
Vice Chair

Email: PRS@hscni.net

Enclosures: List of names and professions of members who took part in the review
 "After ethical review – guidance for researchers" [SL-AR2]

Copy to: Dr David Gillanders, Chief Investigator, The University of Edinburgh
 Ms Charlotte Smith, The University of Edinburgh
 Lead Nation: Scotland - nhsq.NRSPCC@nhs.net

Appendix 1C: Study Proposal (University R1 form)



Doctorate in Clinical Psychology

Thesis Research Proposal (Research 1 Assessment)

This form should be completed and submitted as the assessment for Research 1. It will then be reviewed by a member of the academic team and will receive a grade and detailed feedback. The feedback will include an evaluation of the viability of the project and any recommendations. If there are significant concerns about viability, the project will be flagged to the research director and the research committee will decide whether the project can proceed in its current form.

Exam Number

B137589

Provisional Thesis Title

Psychological Flexibility in Caregivers of People with Acquired Brain Injury

Proposed Setting

Online and NHS - Neuropsychology Department.

Allocated Thesis Project Supervisors

Clinical X

Academic 1 X

Academic 2

**Others
Involved**

Anticipated Month / Year of Submission

Must be final year for full-time trainees. For flex trainees, the month and year of submission will depend on the individual Training and Development Plan. Trainees from 2011 intake onwards must submit in May. Trainees who started in 2010 or earlier are advised to submit in May to reduce potential for HCPC registration difficulties.

March 2021

Please Note: Whilst this is not an ethics review process, where questions have some similarities to questions contained in the NHS IRAS Research Ethics form, the corresponding IRAS question numbers are given in parentheses. This is intended to facilitate completion of NHS ethics where such approval is needed.

Section 1: Introduction

1.1 Provide a brief critical review of relevant literature, which should clearly demonstrate the rationale and scientific justification for the research

1000 – 1500 words

Relevant to IRAS A12

Word count: 1481

Acquired Brain Injury (ABI) is a considerable public health problem and one of the leading causes of lifelong disability and death (Chan, Parmenter, & Stancliffe, 2009). ABI can result in significant impairment of functioning in a range of domains including emotional regulation, behavioural control, cognition and memory, and it can lead to a range of physical and sensory difficulties (Lezak, Howieson, & Loring, 2004). Family and friends often take on the role of caregiver in various capacities including emotional support, medical care and assistance with basic activities of daily living (Talley & Crews, 2007). Depression, anxiety and reduced quality of life (QoL) is common among caregivers of people with ABI and has been found to persist over time (Calvete & De Arroyabe, 2012; Jeffrey S. Kreutzer et al., 2009; Ponsford & Schönberger, 2010). In fact, when compared to other chronic conditions, such as cancer and dementia, caregivers of people with ABI report worse outcomes (Harding et al., 2015; Jackson, Turner-Stokes, Murray et al., 2009). Moreover, caregiver distress has been found to impact negatively on the neuropsychological recovery of the survivor (Covey, Noble, & Schenk, 2013; Greenwood, Mackenzie, Cloud, & Wilson, 2008; Vogler, Klein, & Bender, 2014), which further highlights the importance of research into the effects of ABI beyond the individual patient.

Predictors of caregiver outcomes

Although distress is common in caregivers of people with ABI, not everyone suffers adverse outcomes (Wells, Dywan, & Dumas, 2005). Research into potential factors that contribute to caregiver distress has focused on factors relating to the injury, the care-recipient and caregiver. Severity of injury, or type of ABI, appears to be a weak predictor of caregiver psychological distress or quality of life beyond the acute phase following the injury (Jackson et al., 2009; Kreutzer, Gervasio, & Camplair, 1994; Sander, High, Hannay, & Sherer, 1997). Level of functional disability of the survivor, as perceived by the caregiver, has in some studies been associated with levels of distress (Kreutzer, Serio, & Bergquist, 1994) and QoL (Chronister et al., 2016), whilst other studies have not found this link (Low, Payne, & Roderick, 1999).

Variables within the caregiver are of particular interest as these could be modifiable targets for interventions to alleviate stress. Despite a consistent growth in publications in this area, lack of a unifying theoretical framework limits our ability to synthesise and

translate findings from process research into interventions. Suitable theoretical frameworks for this purpose could be the Stress-Process Model and The Psychological Flexibility Model.

The Stress-Process Model (SPM)

Based on Lazarus and Folkman's (1984) transaction theory, the SPM has been proposed to explain stress in caregivers of people with traumatic brain injury (TBI; Chronister & Chan, 2006; Chwalisz, 1992). This model suggests that cognitive appraisals, coping and social support are central processes associated with caregiver outcomes. According to this model, perceived burden has been conceptualised as the individual's subjective negative *appraisal* of the stressful caregiving situation (Chwalisz, 1996). Perceived burden has been found to be a strong predictor of psychological distress and QoL in caregivers of people with ABI (Bakas & Burgener, 2002; Chronister, Chan, Sasson-Gelman et al., 2010; Harris, Godfrey, Partridge et al., 2001; Sander et al., 1997). Perceived burden has also been found to mediate the relationship between functional disability of the care-recipient and QoL of the caregiver (Chronister et al., 2016).

A further element of the SPM is coping. Coping strategies have been linked to caregiver outcomes, but less is known with regards to what constitutes effective coping among caregivers of ABI (Kendall & Terry, 2008). For example, it has been suggested that problem-focused coping is associated with reduced distress in caregivers of people with TBI (e.g. Chwalisz, 1996), whereas other studies have found the opposite effect (e.g. Chronister & Chan, 2006). Similar inconsistencies have been found for emotion-focused coping (Chwalisz, 1996; Sander et al., 1997). Avoidant coping has consistently been associated with poor psychological adjustment and reduced QoL in caregivers of people with ABI (Blankfeld & Holahan, 1999; Chronister et al., 2010; Wade et al., 2001).

Social support is another element of the SPM which has been argued to serve as a buffer against caregiver distress following ABI. Social support has also been found to moderate outcomes such as QoL and psychological distress (Chronister et al., 2016; Ergh, Rapport, Coleman et al., 2002).

The SPM has established several key constructs linked to caregiver outcomes. However, there are several discrepancies in the findings. Due to the focus on cognitive appraisals and coping strategies, Cognitive Behavioural Therapy (CBT) has been suggested as a suitable intervention involving cognitive restructuring, adaptive strategies and psychoeducation (Bakas & Burgener, 2002). There have been only a few intervention trials using aspects of CBT based on the SPM with inconclusive findings (Boschen et al., 2007; Kreutzer et al., 2009). Thus, new concepts that could link theory to interventions for this population are needed.

Acceptance and Commitment Therapy (ACT) and Psychological Flexibility (PF)

ACT is an empirically based behavioural therapy targeting the function of difficult thoughts, emotions and experiences, rather than striving to change the content of these (Hayes, Strosahl, & Wilson, 1999). ACT aims to foster PF, which is defined as an

individual's ability to experience and accept internal and external events, and to be persistent in actions consistent with personal values, even under difficult circumstances (Harris, 2006). PF involves six overlapping and interdependent processes together referred to as the Hexaflex model: committed action, present moment awareness, values, acceptance, defusion and self as context (Hayes, Luoma, Bond et al., 2006). More recently, PF have been conceptualised as three clusters (open, aware and active) where flexibility is thought to increase through a more open, aware and engaging approach to life (Hayes, Strosahl, & Wilson, 2012).

Higher levels of PF have been associated with lower levels of distress and improved QoL in clinical samples and in the general population (Kashdan & Rottenberg, 2010; Stabbe, Rolfs, & Rogge, 2019). Similarly, ACT has been found to be an effective intervention for a range of conditions, particularly chronic conditions (A-Tjak et al., 2015; Arch et al., 2012; Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011). Studies investigating change mechanisms have found that ACT works through increasing PF (Wicksell, Olsson, & Hayes, 2010).

ACT has shown promising results in alleviating distress in individuals caring for someone with dementia (Kishita, Hammond, Dietrich et al., 2018; Márquez-González, Romero-Moreno, & Losada, 2013). Losada et al. (2015) compared ACT to CBT in an RCT and found both interventions efficacious. Cross-sectional studies have shown that PF is associated with satisfaction of life in dementia caregivers, and that levels of PF mediates the relation between care-recipient function and psychological distress in caregivers (Romero-Moreno, Márquez-González, Losada et al., 2015; Spira, Beaudreau, Jimenez et al., 2007). Similarly, Jansen and colleagues (2017) found PF to predict distress in caregivers of people with psychosis even when controlling for established constructs, such as perceived burden. The above-mentioned studies have measured PF using instruments capturing specific sub-processes, such as acceptance or valued living, and there has been a call for research capturing the concept of PF as a whole which is now possible due to the development of new measures.

Furthermore, there is a lack of research into PF, or ACT, for caregivers of people with ABI. Williams et al. (2014) published a qualitative preliminary investigation into the experience of five spousal caregivers taking part in an ACT group. The authors noted that participants described engaging in strategies to avoid their own emotions prior to the group. Participation in the group was reported to be beneficial as it helped facilitate awareness and acceptance of emotions involved in the caregiving experience. This is also in line with other qualitative accounts of caregiving in ABI where acceptance, living in the present and engagement in value-based behaviours have been identified as themes linked to better adjustment (Abrahamson, Jensen, Springett et al., 2017; Hayas, De Arroyabe, & Calvete, 2015; Lond & Williamson, 2018).

Rationale and aims of the present study

Psychological distress and reduced QoL is common in caregivers of people with ABI but there is a lack of research linking theory with interventions. Established constructs within the SPM are known to predict outcomes in caregivers of a range of conditions but they have not been specifically investigated in the ABI population. PF has been shown to be a

promising new construct to predict caregiver outcomes, and ACT has indicated efficacy in dementia caregivers. However, no research on PF has been carried out in caregivers of people with ABI, although preliminary qualitative evidence indicates the importance of PF and potential usefulness of an ACT approach in this population. Thus, the present study aims to be the first study to examine the association between PF and outcomes in a sample of caregivers of people with ABI. The study will investigate if the full concept of PF predicts caregiver outcomes even when established constructs are controlled for (e.g. perceived burden, coping, social support and functional disability).

Section 2: Research Questions / Objectives

2.1 What is the principal research question / objective?

IRAS A10

1) What is the relative strength of PF, compared to well-established constructs from the SPM, in predicting distress and QoL in caregivers of people living with ABI?

2.2 What are the secondary research questions / objectives, if applicable?

Keep these focused and concise, with a maximum of 5 research questions

IRAS A11

2) Does psychological flexibility moderate relations between established constructs and caregiver outcomes?

Section 3: Methodology

3.1 Give a full summary of your design and methodology

It should be clear exactly what will happen at each stage of the project

IRAS A13

Design

The study will employ a quantitative, cross-sectional design. Participants will be asked to complete a battery of self-reported questionnaires (see 3.4 for details of measures). Ethical approval will be sought through an NHS IRAS application.

Recruitment

Recruitment will be carried out through the local NHS Neuropsychology Department and through advertisement from local and national third-sector organisations.

For the local NHS Neuropsychology Department, posters and flyers will be produced and displayed in suitable locations, such as waiting areas. The researcher's two clinical supervisors will also be able to identify potential participants through their caseloads. Information about the study will be shared with wider multidisciplinary teams (MDT) within the Neurorehabilitation service to encourage recruitment by other team members such as Occupational Therapists or nursing and medical staff, as well as Clinical Psychologists/Neuropsychologists. For this purpose, the researcher will attend MDT meetings in person to explain the purpose of the study and to answer any questions.

For local third-sector organisations, recruitment will be carried out on location using posters and flyers and through meetings with staff. The researcher has already established contact with a local third-sector organisation which supports families and individuals affected by ABI. This organisation has offered to advertise the study through their carers email-list and through social media platforms such as Twitter and Facebook. Two further local third-sector organisations supporting carers have been approached for the same purpose.

National third-sector organisations have been approached to aid recruitment through advertisement of the study. It was thought that this would result in a geographically diverse sample which would capture the many different conditions and heterogeneity of ABI caregivers. Contact has already been established with three national organisations (Headway UK, the Encephalitis Society and Meningitis Now) who have all agreed to support recruitment by advertising the study in their newsletters, on social media platforms (Twitter and Facebook) and by advertisements under the research section on each of the organisations websites.

Procedure

Participants will have the option of completing the questionnaires either by pen and paper or online through an online survey platform. The paper and online versions of the questionnaires will be identical. If participants choose the pen and paper format, they can complete the set of questionnaires either at the location where they obtained the pack or in their own home. Paper versions can either be returned using a pre-paid addressed envelope or by returning them in person to the location where they were obtained.

On the first sheet, participants will first be provided with written information regarding the aims and purpose of the study, what they can expect from participation, how they can obtain the results from the study and their right to withdraw their participation. Informed consent will be obtained from all participants, online this will be done using several questions to ensure participants have understood all information about participation. After completing the set of questionnaires, participants will be presented with a debrief page (or sheet) detailing relevant contact information should they experience any distress from participating in the study.

3.2.1 In which aspects of the research process have you actively involved, or will you involve, patients, service users and/or their carers or members of the public?

Highlight as appropriate.

IRAS A14-1

<u>Design of the research</u>	Analysis of results
Management of the research	<u>Dissemination of findings</u>
<u>Undertaking the research</u>	None of the above

3.2.2 Give details of involvement, or if none, please justify the absence of involvement

Design

Initially, Headway UK was approached for input into the design of the study but was not able to comment on any details of the design due to not being a research led organisation. At this time, the researcher has arranged to meet with the Chief Executive of a local third-sector ABI organisation to discuss the study and to propose a focus group consisting of caregivers. The focus group could help to provide feedback which will be taken into consideration. Specifically, advice will be sought on the wording of the information and inclusion/exclusion criteria to ensure participants feel confident in determining if they meet these without guidance.

Undertaking the research

A small pilot trial will be set up where caregivers have the chance of providing expertise feedback on their experience and highlight any issues. For the main study, caregivers of people with ABI will be involved in undertaking this research project by directly providing data to allow for answering the present research question.

Dissemination

Please see section 8.1 for details regarding dissemination of findings.

3.3 List the principal inclusion and exclusion criteria

IRAS A17-1 and IRAS A17-2

The inclusion and exclusion criteria for eligibility and participation in the present study are outlined below:

Inclusion criteria

- Being an unpaid caregiver
- Caring for a person that:
 - Is over the age of 16
 - Has suffered from an acquired brain injury of any kind (e.g. traumatic brain injury, stroke, sub- arachnoid haemorrhage, anoxia, infectious or metabolic disease, or mixed ABI) that occurred after the age of 16.
 - Has been discharged from hospital (in relation to the ABI) for more than 3 months

Exclusion criteria

- The person cared for has a diagnosis of a degenerative or progressive neurological condition or disease (e.g. any type of dementia, multiple sclerosis, Parkinson's disease, motor neuron disease or recurrent brain tumours).
- The caregiver has insufficient ability to comprehend written English

The wording of these criteria might be adapted to ensure participants are able to independently determine if they are eligible for participation.

3.4 How will data be collected?

If quantitative, list proposed measures and justify the use of these measures. If qualitative, explain how data will be collected, giving reasonable detail (don't just say "by interviews".)

Below are all independent and dependent variables with associated measures that will be administered in either paper format or through an online survey platform.

Independent Variables

Psychological Flexibility: Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT)

The CompACT is a self-reported newly developed scale designed to assess psychological flexibility (PF), the core process in ACT (Francis, Dawson, & Golijani-Moghaddam, 2016). The scale comprises of 23-items and respondents are asked to rate each item from 0 (*strongly disagree*) to 6 (*strongly agree*). The CompACT includes three subscales assessing specific, but inter-related, processes involved in the overarching concept of psychological flexibility namely: Openness to Experience, Behavioural Awareness and Valued Action. Thus, the CompACT's subscales are linked to the more recent theoretical conceptualisation of PF as being three broad clusters: open, aware and active (Hayes et al., 2012). The range of scores for each subscale are 0-60 for Openness to Experience, 0-30 for Behavioural Awareness and 0-48 for Valued Action. Higher scores indicate greater psychological flexibility, and the instrument can be interpreted as one total score or using scores for each subscale. The complete CompACT has been found to have excellent internal consistency ($\alpha = .91$) and good convergent validity ($r = .79$) with the Acceptance and Action Questionnaire-II (AAQ-II; Bond et al., 2011), which is an established ACT measure. Cronbach's alpha for each subscale ranges from .87 to .90 (Francis et al., 2016).

The CompAct was selected for the present study due to its ability to assess core ACT processes using one instrument. Most instruments used in ACT research are typically circumscribed to one particular theoretical sub-process, such as the AAQ-II or the Valued Living Questionnaire (Wilson, Sandoz, Kitchens et al., 2010). Although these instruments have utility in measuring individual processes it becomes impractical to administer six full-scale process measures to capture the full theoretical ACT model. Further, the CompACT has good discriminant validity to distress measures, which has been a critique of some other ACT measures (Wolgast, 2014).

Appraisal - Perceived Burden: the Modified Caregiver Appraisal Scale (MCAS)

The MCAS was developed to assess subjective appraisal of present caregiver experience (Struchen, Atchison, Roebuck et al., 2002). The complete MCAS is comprised of 35 items with each item being rated on a 5-point Likert-type scale where respondents are asked to rate how much they agree with each item by choosing from 1 (*strongly disagree*) to 5 (*strongly agree*). The complete MCAS includes 4 sub-scales (i.e. Perceived Caregiving Burden, Perceived Caregiving Mastery, Perceived Caregiving Satisfaction and Perceived Caregiving Ideology). Struchen and colleagues (2002) developed and validated the MCAS on a sample consisting of caregivers of people with TBI and reported good psychometric

properties. The MCAS was selected for the present study as it measures appraisal directly related to the caregiving situation and is developed based on accepted theories of stress appraisal where perceived burden is a central concept.

For the present study, the perceived caregiving burden sub-scale will be used to measure appraisal which is comprised of 15 items (e.g. *I have lost control of my life since this individual's injury*). The total score ranges from 15 to 74, with higher scores indicating lower perceived burden. The perceived burden scale has been shown to have good internal consistency ($\alpha=.91$), test-retest reliability ($r=.78$) and convergent validity with other subjective burden scales (Lawton, Kleban, Moss et al., 1989; Struchen et al., 2002). The perceived caregiving burden scale was selected to measure appraisal in the present study due to perceived burden being an established construct shown to predict caregiver outcomes based on the SPM (Chwalisz, 1992;1996), and as it has been found to mediate the relationship between care-recipient functional disability and caregiver QoL (Chronister et al., 2016).

Coping: The brief Coping Orientation to Problems Experienced (COPE) scale

The brief COPE is a self-reported questionnaire measuring an individual's preference for coping strategies (Carver, 1997). Respondents are asked to rate on a 4-point Likert-type scale how frequently they use a specific coping strategy to manage stress associated with a particular situation (e.g. caregiving). An example of an item is "*I've been expressing my negative feelings*" and answers range from 1 (*not doing it at all*) to 4 (*doing it a lot*). The brief COPE has a similar factor structure to the longer original instrument which is comprised of 60 items including 15 sub-scales (e.g. humour, use of instrumental support, denial) with 4 items per sub-scale. The original COPE has acceptable test-retest reliability and internal consistency for the subscales range from .62 to .92 (Carver, Scheier, & Weintraub, 1989; Wade et al., 2001). The brief COPE is comprised of 28 items including 14 subscales from the longer version but with 2 items per scale.

For the present study, the items of the brief COPE will be grouped into three scales to measure different coping strategies: emotion-focused (e.g. humour, religion), problem-focused (e.g. instrumental support, planning) and avoidant coping (e.g. denial, self-blame). The score range is 10 to 40 for emotion-focused, 6 to 24 for problem-focused and 12 to 48 for avoidant coping. Although Carver et al. (1989) suggested exploring each one of the 14 scales, evidence has been found for the above three factors and this approach is now a common method to measure coping styles (Chronister et al., 2010; Livneh & Wilson, 2003). Further, Cooper and colleagues reported good internal consistencies for emotion-focused, problem-focused and avoidant coping subscales ($\alpha = 0.72, 0.84, 0.75$ respectively) when investigating psychometric properties of the brief COPE in a sample of caregivers (Cooper, Katona, & Livingston, 2008).

Functional Disability: the Patient Competency Rating Scale – Relative Version (PCRS – RV)

The PCRS-RV was developed by Prigatano (1986) to assess functional competency of the care-recipient including activities of daily living, emotional regulation, interpersonal and cognitive functioning as perceived by the caregiver. The PCRS is comprised of 30 self-

reported items (e.g. *how much problem do they have in understanding new instructions?* or *how much problem do they have in washing the dishes?*) where the caregiver rates the relative difficulty on a 5- point Likert-type scale, ranging from 1 (*can't do*) to 5 (*can do with ease*). Total scores range from 30 to 150. For the present study, the scale will be administered as a measure of functional disability and the scores will be reversed, with higher scores indicating greater functional disability as perceived by the caregiver. The PCRS has been utilised in a number of studies on ABI caregiver outcomes (e.g. Chronister et al., 2006; 2016). Acceptable test-retest reliability (.92), internal consistency (.93) and associations with the Glasgow Coma scale have been reported (Ergh, Rapport, Coleman et al., 2002; Fleming, Strong, & Ashton, 1998; Sandhaug, Andelic, Berntsen et al., 2012).

The PCRS-RV was selected for the present study as it has been used in previous research on predictors of caregiver distress and QoL in a ABI population, and it is a routinely used measure in the local NHS Neuropsychology Department where some of the recruitment will take place. The construct validity of the PCRS has been debated and it is important to stress that this measure evaluates the *caregiver's* perception of disability or competency (Prigatano, 1986).

Social Support: The Interpersonal Support Evaluation List-12 (ISEL-12)

The ISEL-12 is a brief version of the 40-item long ISEL (Cohen & Hoberman, 1983; Cohen, Mermelstein, Kamarck et al., 1985). ISEL-12 contains 12 self-reported items assessing perceived available social support on a 4-point Likert-type scale ranging from 0 (definitely false) and 3 (definitely true). An example item is: "*If I needed help fixing an appliance or repairing my car, there is someone who would help me*". Total score ranges are 0-36. The items are counterbalanced to desirability in that half the items are positive statements and the other half are negative. Higher scores indicate higher social support. Internal consistency has been reported as acceptable ($\alpha = .77$), and the scale has been widely used to assess ABI caregiver support (Chronister et al., 2010; Cohen & Hoberman, 1983; Stevens et al., 2013).

Dependent Variables

Life Satisfaction: Satisfaction With Life Scale (SWLS)

The SWLS (Diener, Emmons, Larsem et al., 1985) is a self-report measure designed to assess perceived global life satisfaction. Respondents are asked to judge five life satisfaction statements (e.g. *the conditions of my life are excellent*) on a 7-point Likert-type scale from 1 (strongly disagree) to 7 (strongly agree), with a possible range of scores between 5 (low satisfaction) to 35 (high satisfaction). Normative data for the SWLS are available for diverse populations including caregivers (Vitaliano, Russo, Young et al., 1991). The SWLS has been found to have good internal consistency and test-retest reliability (Diener et al., 1985; Pavot, Diener, Colvin et al., 1991). Vitaliano et al. (1991) reported evidence that scores on the SWLS respond to changing life conditions in caregivers of people with dementia, whilst measures of anxiety and depression did not. This finding not only illustrates construct validity of the SWLS, but also that it is useful to consider life satisfaction as an outcome in research on caregivers in addition to measures

of psychological distress. Similarly, the SWLS has been recommended as a good complement to scales of QoL as it captures an individual's evaluative judgment of their life based on their own criteria and personal values (Pavot & Diener, 2008), which is moreover a suitable measure of outcome when examining ACT processes.

Health-Related Quality of Life (HRQoL): The Euro-QoL 5 (EQ-5D)

The EQ-5D is a brief generic health status questionnaire developed by the multinational research group Euro-Qol (The EuroQol Group, 1990). The instrument is comprised of 5 self-rated domains relevant to HRQoL and a visual analog scale (VAS). The 5 domains include: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain has five levels and respondents select the level which matches their health state (e.g. *I have slight pain or discomfort*). For the VAS, respondents are asked to mark their current health status on a 100-point visual scale where 100 represents "the best health you can imagine" and 0 represents "the worst health you can imagine". The EQ-5D has good test-retest reliability ($r=.71-.80$), convergent validity with the WHO-5 (Bech, Olsen, Kjoller et al., 2003) and has been used in ABI caregiver research (Janssen et al., 2013; Van Agt, Essink-Bot, Krabbe et al., 2005; Vogler, Klein, & Bender, 2014).

The EQ-5D was selected as an outcome measure in the present study to assess how predictor variables impact on general health status of ABI caregivers. Studies on caregivers of people with ABI have found reduced HRQoL from long-term caregiving (Vogler et al., 2014). Further, HRQoL was deemed to be an appropriate complement to the SWLS scale which instead captures value-based satisfaction with life.

Psychological Distress: the Depression Anxiety Stress Scale (DASS-21)

DASS-21 is an established measure assessing three separate constructs of psychological distress: Depression; Anxiety; and Stress (Antony, Cox, Enns et al., 1998; Lovibond & Lovibond, 1995). DASS-21 is comprised of 21 self-reported items with 7 items for each construct. Each item is rated on 4-point Likert-type scale ranging from 0 (*does not apply to me at all*) to 3 (*applied to me very much, or most of the time*). Respondents are asked to estimate how much every item applies to them based on the past week with higher scores indicate higher distress. The DASS-21 has been shown to have adequate internal consistency with Cronbach's alpha of .88, .82 and .90 for the depression scale, anxiety scale and stress scale, respectively (Henry & Crawford, 2005). Validity has been suggested through comparison with Beck Depression Inventory (Beck, Steer, & Brown, 1996) where a correlation of .69 for stress scale, .79 for depression scale and .62 for anxiety scale has been found (Antony et al., 1998). The DASS-21 has been considered advantageous over other distress measures (e.g. HADS) due to superior psychometric properties and its additional ability to measure a stress dimension (Sukantarat, Williamson, & Brett, 2007).

Section 4: Sample Size

4.1 What sample size is needed for the research and how did you determine this?

For quantitative projects, outline the relevant Power calculations and the rationale for assuming given effect sizes. For qualitative projects, outline your reasoning for assuming that this sample size will be sufficient to address the study's aims

IRAS A59 and IRAS A60

The minimum sample size required to achieve sufficient power will be determined a-priori based on multiple sources and methods whilst considering the nature of the different questions.

Primary question: *What is the relative strength of PF, compared to well-established constructs from the SPM, in predicting distress and QoL in caregivers of people living with ABI?*

Firstly, G*power 3.1 was utilised to determine minimum required sample size to conduct a multiple regression analysis of the IVs on the DVs (Faul, Erdfelder, Buchner et al., 2009). For this calculation, alpha level was set to .05, statistical power was set to .80 and five predictors were included (i.e. psychological flexibility, perceived burden, coping, social support and functional disability). Effect size was set to medium (i.e. 0.13; Cohen, 1988) as this has been observed in previous research investigating these predictors in a similar population (e.g. Chronister et al., 2016). This calculation estimated a minimum sample size of 105 to achieve sufficient power to detect a medium effect size.

Secondly, power tables for multiple regression (Clark-Carter, 2009) were matched with the above estimation which suggested a sample size of between 90 and 100 participants to detect a medium effect size (power = .81) with five predictors.

Thirdly, Green's (1991) rules of thumb were considered. Green suggests $N \geq 50 + 8m$, where m is number of predictors, for testing multiple correlation. Green also suggests using $N \geq 104 + m$ for a partial correlation between a DV and a predictor whilst holding all other predictors constant. Using this calculation, sufficient power (.80) should be achieved to detect a medium effect size. Thus, for the present study a minimum sample size of 109 should be sufficient.

Secondary questions

For secondary questions, moderation/mediation analyses will be conducted using conditional process analysis (Hayes, 2013). Fritz and MacKinnon (2007) was referred to in order to determine a sample size that would achieve enough power (.80) to detect a medium effect size in a simple model. Estimating medium effect size was based on strengths of correlations between established variables in previous research for functional disability of care-recipient, perceived burden and QoL (Chronister et al., 2016). Unfortunately, no previous data are available for correlations of psychological flexibility in this population. According to Fritz and MacKinnon's table, a minimum sample size of 75 would be required.

Conclusion

Considering the above estimations, particularly the higher numbers, a sample size of 109 is recommended. However, issues such as incomplete questionnaires will inevitably occur, and to account for this a minimum sample size of between 110 and 115 participants will be aimed for.

4.2 Outline reasons for your confidence in being able to achieve a sample of at least this size

E.g. give details of size of known available sample(s), percentage of this type of sample that typically participate in such studies, opinions of relevant individuals working in that area

Due to the sample size required for the present study it has been a high priority to seek out as many avenues for recruitment as possible. Recruitment nation-wide and by using both paper and online questionnaires will increase the chance of achieving the intended sample size. Similarly, twelve months will be allowed for recruitment.

Contact has been established with several third sector organisations which have agreed to support recruitment by advertising the study using several approaches. On a national level, Headway UK, Meningitis Now and The Encephalitis Society has a large combined membership on social media (Facebook = 115 000, Twitter = 42 000) and they reach thousands of members monthly or quarterly through their email newsletter. Further, they have all agreed to advertise the study on their websites which will ensure continuous exposure throughout the recruitment window. The response from these organisations have been highly positive and they have stated that their members often are happy to engage with research, particularly carers. Only the Encephalitis Society could provide an approximate estimate on previous recruitment rate through their website. The Director of Operations stated that a recent project, recruiting only through the Encephalitis Society, achieved a sample just over 100 participants through the website for a study with a narrower inclusion criteria than the present study. On a local level, contact has been established with an organisation who has agreed to help advertising the study through their newsletter which is sent out to hundreds of caregivers of people with ABI.

The researcher's clinical supervisor has estimated that it is reasonable to expect that approximately 30 participants could be recruited from the local NHS Neuropsychology Department. Continuous encouragement to identify eligible participants will be undertaken via regular visits to the different sites and through participation in MDT meetings throughout the recruitment window.

Section 5: Analysis

5.1 Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative methods) by which the data will be evaluated to meet the study objectives

IRAS A62

Dissemination											
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? = subject to change, * = planned leave within month

Section 7: Management of Risks to Project

7.1 Summarise the main potential risks to your study, the perceived likelihood of occurrence of these risks and any steps you will or have taken to reduce these risks. Outline how you will respond to identified risks if they should occur

Failure to recruit intended sample size

The main risk to the present study is not recruiting enough participants. This is considered a medium risk. Efforts have been made at an early stage to establish relationships with organisations that can reach a large number of potential participants. Relative to the project time scale, a long recruitment period has been set out to ensure enough time is allowed for recruitment. To recruit over a long period also allows the researcher to respond early if this would appear to be an issue. Expanding the number of third sector organisations that could advertise the study would be one response to such risk. Another would be to broaden recruitment to other NHS health boards.

Excessive testing burden

It is acknowledged that the current design involves several measures with an estimated completion time of approximately 30 minutes (4.5 items per minute). Thus, the risk of a high testing burden on participants is estimated as a medium likelihood. Brief versions of measures have actively been selected to minimise this risk. Participants will have the opportunity to complete the set of questionnaires in their own time and online, which will improve accessibility and flexibility for the participants.

Time

The researcher is undertaking this project over a relatively short period due to being on the 2.5 years doctorate programme. Time is therefore limited, and feasibility timewise has been a priority since the start of the project. The risk of running out of time is considered medium likelihood. However, as described in the GANTT chart above, time has been estimated as sufficient for completion of the project on time.

Reliance on other parties

There is some degree of reliance on other parties, particularly in terms of advertising the study. In terms of third-sector organisations, the response has been positive with organisations being encouraging. It will be essential to maintain relationships with both the NHS Neuropsychology Department and third-sector organisations, which will require time and effort.

Rejection of ethical approval leading to reduced recruitment period

The likelihood of this risk is regarded as low, but would have a large impact if it occurs. To ameliorate this risk support will be sought from NHS staff with expertise in the ethics process, and advice will be sought from clinical supervisors due to their knowledge of the participant population.

Participants may experience high levels of psychological distress

This risk is estimated as a low due to the nature of the questions and design of the study. However, relevant contact details for support will be included in the debrief sheet as part of the study.

Section 8: Knowledge Exchange

8.1 How do you intend to report and disseminate the results of the study?

IRAS A51

A research article based on the results of this study will be prepared and submitted for publication in a relevant journal. Due to the nature of the research topic relevant journals could be within, for example, the field of rehabilitation, caregiving, brain injury, nursing or contextual behavioural science.

Presentations and poster events will be actively sought out to disseminate findings of the study. For example, Headway UK has several yearly events and conferences, such as “The Way Ahead”. These events would be a good opportunity to disseminate findings to a wide audience from Headway groups across the UK including committee members, trustees, service providers and carers. Similarly, Brain Injuries Rehabilitation Trust annual conference is another event suitable for dissemination. Presentations at local NHS departmental CPD events would be another source for dissemination.

As part of completing the study, participants will be provided with contact details to the researcher and encouraged to get in contact to find out the results of the project. A lay-summary of the findings and a link to the article will also be provided to all organisations that advertised the study to ensure the results are shared with the same population that engaged in the research.

8.2 What are the anticipated benefits or implications of the project?

E.g. if this is an NHS project, in what way(s) is the project intended to benefit the NHS?

Research has shown that caregivers of people with ABI report emotional support needs as being unmet and that they, and their loved one, would benefit from interventions targeting their own emotional adjustment and distress (Powell et al., 2017; Tverdov, et al., 2016). Thus, more research based in established theories could benefit future research and development of caregiver interventions, which is needed for this population. Thus, caregivers within and outwith the NHS could benefit from research such as the present study.

Clinical Psychologist working within Neuropsychology Departments often work systemically to implement packages of care where the mental health of caregivers is essential for a successful implementation. Thus, if Clinical Psychologists can recognise distress in caregivers early on then crises could be avoided. Further, by knowing more

about the ability of PF for this population pathways could be developed and interventions such as caregiver groups could be implemented to reduce caregiver distress which could improve success rates for packages of care in the community.

8.3 Are there any potential costs for the project?

Outline any potential financial costs to the project, including the justification for the costs (why are these necessary for the research project?) and how funding will be obtained for these costs (how will they be met?) Please separate these into potential costs for the University and potential costs for your NHS Board and note that you should ask your NHS Board to meet stationery, printing, postage and travel costs.

At this time, the below activities have been identified to involve a cost and funding for these will be applied through the NHS or the University of Edinburgh.

- Printing of paper versions of questionnaires, included information and debrief sheets
- Printing posters and flyers
- Stamps and envelopes for paper versions of the questionnaires

Section 11: Confirmation of Supervisors' Approval

"I confirm that both my Academic and Clinical Supervisors have seen and approved this research proposal and have both completed the supervisors' appraisal forms below."

Delete as appropriate

Yes	
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Main Academic Supervisor's Appraisal of Project Risk

Date

21st May 2019

Do you consider that the project should proceed in broadly its current form?

Delete as appropriate

Yes		
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Outline the reasons for the above response

Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks

This study has benefited from significant work up by the trainee, in collaboration with me as academic supervisor and two field supervisors. Due consideration has been given to the background literature, a research gap and associated question has been identified and the methods are capable of answering the question. Recruitment is the biggest risk, to that end this trainee has already started to develop the network of collaborators and I think that this mitigates the risk substantially. The topic is within the research programme of the academic supervisor and within the area of clinical expertise of the field supervisors and as such has a good chance of success.

Clinical Thesis Supervisor's Appraisal of Project Risk

Date

 20th May 2019

Do you consider that the project should proceed in broadly its current form?
Delete as appropriate

Yes		
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Outline the reasons for the above response

Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks

Risks:

- 1) Failure to recruit enough participants within given timeframe: The current project has set a broad criteria for recruitment of participants and already organised meetings with relevant organisations regarding this.

Lay Summary

Provide a summary of your project in language suitable for a layperson

500 words

Acquired Brain Injury (ABI) is an injury to the brain that occurred after birth including Traumatic Brain Injury (TBI), stroke, meningitis or encephalitis to name a few. ABIs can have long-term effects on the survivor with impairments in several areas of a person's life such as memory, emotion, behaviour and personality. It is common that people around the ABI survivor, including friends and family, take on the role of caregiver which could include emotional support, medical care and assistance with activities of daily living. Research has shown that psychological distress (e.g. anxiety or depression) and reduced quality of life is commonly found in caregivers of people with ABI, and even more so than in caregivers of other long-term conditions such as cancer or dementia.

Research has tried to find out more about what factors play a role in explaining caregiver distress and reduced quality of life. Factors within the caregiver are of particular interest as these would potentially be targets for new interventions and psychological treatments that could aim to reduce psychological distress and increase quality of life.

One known factor that will impact on caregiver distress is *how* the caregiver think about the caregiver situation. That is, if the caregiver appraises the caregiver situation as threatening, then this would lead to heightened distress. Similarly, certain coping strategies have been found to be associated with distress and quality of life. For example, if the caregiver relies on coping strategies that involves avoidance of difficult situations or feelings (e.g. denial) then this can result in more distress and reduced quality of life.

Another known factor that impacts on the caregiver distress is how much social support the caregiver knows they have, or do not have. More social support has been associated with better quality of life.

More recently, Acceptance and Commitment Therapy (ACT) has been shown to be helpful to reduce distress in caregivers of people with dementia. Within ACT, people learn how to relate to experiences in an open and aware manner, even if these experiences are difficult such as caregiving. People also learn techniques to help them move towards their values in life even under difficult circumstances. By doing this, it is thought that one becomes more psychologically flexible. Psychological flexibility is thought to lead to less distress and a better quality of life, which has been found in research on dementia caregivers.

The aim of this study is to explore how psychological flexibility can explain distress and quality of life in caregivers of people with ABI. Participants will be recruited from an NHS Neuropsychology Department and through several third-sector organisations. Every participant will be invited to complete a set of questionnaires, each questionnaire assessing factors that could impact on caregiver outcomes. Questionnaires will be administered either online or by pen and paper. We hope that by knowing more about the potential ability of psychological flexibility in this population, this can inform NHS services and other agencies that could provide support for caregivers of people with ABI.